

EXHIBIT 3

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
MDL NO. 2875

-----X
IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

All Actions

Case No. 1:19-md-02875-RBK-SAK
-----X

VIDEO DEPOSITION OF : RON NAJAFI

February 3, 2022

* * * * *

TRANSCRIPT of the videotaped deposition of the
above-named witness, called for Oral Examination in
the above-entitled matter, said deposition being
taken pursuant to Superior Court Rules of Civil
Practice and Procedure, by and before MICHELLE L.
DAWKINS, CSR, RPR, a Certified Court Reporter and
Notary Public of the State of New Jersey, held
REMOTELY VIA ZOOM on Thursday, February 3, 2022,
commencing at 9:09 a.m. Pacific Standard Time.

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1 THE VIDEOGRAPHER: Good morning. We
2 are going on the record at 9:09 a.m. Pacific time on
3 February 3, 2022. This is Media Unit 1 of the video
4 recorded deposition of Ron Najafi, PhD in regards to
5 the valsartan/losartan litigation which is found in
6 United States District Court, district of New
7 Jersey, NDL No. 2875. My name is William Miller
8 from the firm Veritext Legal Solutions and I am the
9 videographer. The court reporter is Michelle
10 Dawkins from the firm Veritext Legal Solutions. All
11 counsel is noted on the stenographic record. Will
12 the court reporter please swear in the witness.
13 You're on mute, Michelle.

14 THE COURT REPORTER: Sorry. Good
15 morning. My name is Michelle Dawkins and I am the
16 court reporter. The attorneys participating in this
17 deposition acknowledge that I am not physically
18 present in the deposition room and that I will be
19 reporting this deposition remotely.

20 They further acknowledge that in lieu
21 of an oath administered in person, I will administer
22 the oath remotely. The parties and their counsel
23 consent to this arrangement and waive any objections
24 to this manner of reporting.

25 Please indicate your agreement by

1 stating your name and your agreement on the record.

2 MR. TRISCHLER: Clem Trischler. So
3 agreed on behalf of the defendants.

4 MR. NIGH: Daniel Nigh, agreed on
5 behalf of the plaintiffs.

6 THE COURT REPORTER: Would the witness
7 please state his full name.

8 THE WITNESS: My name is Ron Najafi.

9 THE COURT REPORTER: Mr. Najafi, would
10 you please raise your right hand. Do you solemnly
11 swear or affirm the testimony you will give at this
12 deposition will be the truth, the whole truth and
13 nothing but the truth?

14 THE WITNESS: Yes, I do.

15 THE COURT REPORTER: Thank you.

16 DIRECT EXAMINATION

17 BY MR. TRISCHLER:

18 Q Sir, let me start by saying good
19 morning. I think it's morning where you're located,
20 so I'll say good morning to you.

21 A Good morning to you.

22 Q Thank you. My name is Clem Trischler.
23 I am an attorney. I represent one of many
24 defendants in litigation that's pending in the
25 United States District Court for the district of New

1 Jersey involving valsartan.

2 I understand that you've been identified and
3 designated an expert witness in this litigation; is
4 that correct?

5 A That's correct.

6 Q I'd like to maybe start today by
7 covering some basic concepts and see if we can get
8 an agreement on a few basic points. Okay?

9 A Okay.

10 Q Number one, it is an established fact
11 that all drug products contain impurities, agreed?

12 A Yes, they do.

13 Q A drug or a drug substance is not
14 considered misbranded simply because it contains
15 impurities, true?

16 MR. NIGH: Form objection. Outside
17 the scope.

18 A A drug product contains impurities
19 that are harmless and they could also contain
20 impurities that could be extremely hazardous.

21 Q That wasn't my question, sir. See if
22 you can listen to my question and give me an answer
23 to my question, please.

24 A drug product is not considered misbranded
25 simply because it contains impurities; isn't that

1 true?

2 MR. NIGH: Form objection. Outside
3 the scope.

4 A A drug, as I mentioned to you,
5 Mr. Trischler, drug product contains impurities that
6 could be harmless or could be hazardous.

7 Q Is a drug product considered
8 misbranded under federal law merely because it
9 contains impurities?

10 MR. NIGH: Form objection. Outside
11 the scope.

12 A A drug product, as I mentioned,
13 contains impurities that could be harmless or could
14 be hazardous and they could be misbranded because of
15 the hazardous nature of the impurities.

16 Q If a drug product contains impurities
17 that are not harmful to public health, are those
18 drug products considered to be misbranded?

19 A No.

20 MR. NIGH: Form objection. Outside
21 the scope.

22 Q If a drug substance -- every drug
23 substance ever made in America has impurities,
24 correct?

25 A Every drug product that is made in

1 America or anywhere on the planet could contain
2 impurities that are harmless or could be hazardous.

3 Q I didn't ask you that question, sir.
4 I said, isn't it a fact that every drug product ever
5 made in America or on the planet does contain some
6 impurities?

7 MR. NIGH: He answered the question.
8 He answered the question previously and it's outside
9 the scope.

10 MR. TRISCHLER: It's not an
11 appropriate objection. It's not an appropriate
12 instruction, if that's what it was. My question
13 stands -- excuse me. And I'd like an answer.

14 MR. NIGH: Objection. Asked and
15 answered.

16 MR. TRISCHLER: I don't know how you
17 know that, since I haven't asked it yet, but let me
18 try again.

19 Q Every drug product ever made in the
20 United States made for sale in the United States of
21 America contains some impurities. Can we agree on
22 that?

23 MR. NIGH: Objection. Asked and
24 answered.

25 A I already responded to that question,

1 sir.

2 Q I'm asking it again, then, sir. I ask
3 you to answer my question, sir.

4 A Sir, I will give you the same answer.

5 Q What is the answer to my question?

6 A I just gave you the answer to your
7 question. Every drug product or every drug
8 substance that's produced on the planet contains
9 harmless and harmful impurities.

10 Q If the mere presence of an impurity
11 rendered a drug product adulterated and misbranded,
12 then virtually pharmaceutical produced today would
13 be deemed misbranded and adulterated, do you agree?

14 MR. NIGH: Form objection. Outside
15 the scope.

16 A I did not say that. I said --

17 Q I didn't -- sir, let me stop you. I
18 didn't ask you what you said. I asked you a
19 question. Do you understand that this is a question
20 and answer session and I am permitted to ask you
21 questions and you're required to give me responsive
22 answers to those questions; is that a concept you
23 understand?

24 MR. NIGH: Mr. Trischler, you just now
25 interrupted the witness in the middle of his answer.

1 It wasn't completed.

2 Q Do you understand that I am entitled
3 to answers to my questions, sir?

4 MR. NIGH: Do you understand not to
5 interrupt the witness when he's answering your
6 question?

7 MR. TRISCHLER: I'm not going to get
8 into a colloquy with you. I'm talking to the
9 witness. Do you understand --

10 MR. NIGH: Well, please don't
11 interrupt the witness in the middle of his
12 question -- I mean, in the middle of his answer.

13 Q Do you understand that I'm entitled to
14 responsive answers to my question, sir?

15 A Clem, every drug product or drug
16 substance that's produced on the planet contains
17 harmless or harmful impurities. They could be
18 misbranded if it contains extremely harmful
19 impurities and they could not be misbranded if they
20 are not harmful.

21 Q So then you would agree with me that
22 the mere presence of some impurity does not render a
23 drug product misbranded or adulterated, right?

24 MR. NIGH: Scope.

25 A I already responded to your question.

1 I think you should -- I think it's -- the answer is
2 clear.

3 Q Do you agree that the mere presence of
4 an impurity does not render a drug adulterated or
5 misbranded?

6 MR. NIGH: Objection. Scope.

7 A I responded to your question.

8 Q Sir, I am entitled to an answer to the
9 question. I don't know if there was an internet
10 issue. If there is was an answer, I didn't hear it.

11 A There is no internet issues.

12 Q I said I didn't hear. If there was an
13 answer, I did not hear it.

14 MR. NIGH: Was there an answer to the
15 last question, Michelle?

16 A I already answered it.

17 Q I'm not talking to you, sir.

18 A Let's move on to the next question.

19 (The previous testimony as requested
20 was read by the reporter.)

21 MR. TRISCHLER: Okay. Thank you.

22 Q It's not clear to me, so I would like
23 an answer, please. Is it your testimony that the
24 mere presence of an impurity renders a drug
25 misbranded or adulterated; yes or no?

1 MR. NIGH: Again, it's outside the
2 scope.

3 A I already responded to your question.
4 Just look at the record. Go back to the records and
5 you'll see my answer.

6 Q So are you refusing to answer my
7 question, sir?

8 A I already responded to your question.

9 Q No, you didn't. No you didn't. I
10 asked a different question, sir. This is going to
11 be a long day or else we're going to come back and
12 I'm going to get fees, because Magistrate Judge
13 Menaski has talked about obstructionist witnesses
14 like this. So if you don't want to answer the
15 question, that's fine. We'll halt the deposition,
16 I'll get fees for it, and we'll come back here
17 again.

18 The question is pretty simple. Is it your
19 position that the mere presence of an impurity
20 renders a drug adulterated or misbranded; yes or no?

21 MR. NIGH: Object to the colloquy
22 given to the witness. Disagree, but I will ask the
23 witness to answer this question again.

24 A Again, this is not a "yes" or "no"
25 answer, because mere presence of an impurity, if

1 it's safe impurity if it's determined safe, then
2 it's not misbranded, but if it's an unsafe impurity
3 then, yes, it is misbranded.

4 Q Does FDA require the supplier of an
5 active pharmaceutical ingredient used in generic
6 drug to use the same synthetic process used by the
7 RLB holder?

8 MR. NIGH: Form objection.

9 A The FDA does not require the generic
10 manufacturers to use exact procedure of the branded
11 drug.

12 Q When you say "exact procedure," my
13 question as are they required to use the same
14 synthetic process for developing and producing API.
15 The answer is no, correct?

16 MR. NIGH: Form objection. Outside
17 the scope.

18 A Mr. Trischler, am I pronouncing your
19 name right?

20 Q Close enough, sir.

21 A Mr. Trischler, FDA does not require a
22 generic manufacturer to use exact chemical procedure
23 as the brand to synthesize the generic drug.

24 Q And because the synthetic process used
25 by an RLD holder in a generic manufacturer may be

1 different, it's not uncommon or unexpected that the
2 API used in an ANDA will have a different impurity
3 profile than the reference listed drug, is it?

4 MR. NIGH: Form objection. Outside
5 the scope.

6 A It is entirely possible that the
7 impurity profile of the generic drug may be
8 different.

9 Q In fact, there's absolutely no
10 requirement anywhere in the FDA regulations that
11 mandate that an RLD match or mirror the impurity
12 profile of the generic alternative, is there?

13 A The FDA does not require that the
14 generic drug manufacturer to match every impurity of
15 the branded drug.

16 However, they do require that the impurity is
17 to be determined safe. They do require that a
18 generic drug does sufficient due diligence to
19 determine the synthetic path is safe.

20 Q A generic manufacturer can establish
21 and satisfy FDA requirements for bio equivalents
22 even where the impurity profiles between the RLD and
23 the generic equivalent product are different,
24 correct?

25 A Could you repeat your question.

1 Q Yes. A generic drug manufacturer can
2 establish and satisfy FDA requirements for bio
3 equivalents even where the impurity profiles between
4 the RLD and generic equivalent product are
5 different.

6 A The generic drugs have to establish
7 bio equivalence when they make a generic drug.

8 Q Right. And you can --

9 A A bio equivalence does not refer to,
10 you know, impurity profile.

11 Q I understand. My question was bio
12 equivalence can be established in having impurity
13 profiles that match as between the reference listed
14 drug and the generic applicant, correct?

15 A No, I didn't say that.

16 Q Then answer the question.

17 A Repeat your question please.

18 Q Sure. I said that a generic drug
19 manufacturer can meet FDA requirements for bio
20 equivalence without having an impurity profile that
21 matches the impurity profile of the reference listed
22 drug.

23 A The generic manufacturer can establish
24 bio equivalence or a synthetic process irrespective
25 of whether they have -- what kind of impurities they

1 have. They could have harmful impurities, they
2 could have harmless impurities, and they can still
3 establish bio equivalence, but that's irrespective
4 of what kind of impurities they have.

5 Q Does the Food, Drug, and Cosmetic Act
6 contain a definition of an adulterated product?

7 MR. NIGH: Form. Outside the scope.

8 A To me, adulterated products are
9 products that have been contaminated.

10 Q Well, I appreciate your definition,
11 but I'm really not interested in it. My question
12 was, does the Food, Drug, and Cosmetic Act contain a
13 definition of what constitutes adulterated product?

14 A Yes, they do.

15 MR. NIGH: Hold on. Hold on. Object
16 to the colloquy. It's inappropriate. You can
17 answer.

18 A Adulterated products are products that
19 are mislabeled. They don't have proper label and
20 they could have toxic impurity in it, either
21 intentionally or inadvertently, and they could be
22 called adulterated.

23 Q Have you ever read the definition of
24 an adulterated drug product under the Food, Drug,
25 and Cosmetic Act?

1 A Yes, I have.

2 Q Are you familiar with the definition
3 under Section 351 of the Food, Drug, and Cosmetic
4 Act?

5 A I haven't looked at it exactly today,
6 but I am familiar with that.

7 Q Section 351 defined an adulterated
8 drug as one where its strength differs from or its
9 quality impurity fall below the standards set forth
10 in the compendium.

11 A I agree with that.

12 MR. NIGH: Hold on. Was there a
13 question?

14 MR. TRISCHLER: There was.

15 A You just read the definition.

16 Q Right. And you would agree with that
17 definition, right?

18 MR. NIGH: Form objection. Outside
19 the scope.

20 Q You agree with that definition, sir?

21 A If you're reading it from the regs,
22 yes.

23 Q And where there is a USP monograph,
24 any article marketed in the United States must meet
25 the requirements and specifications of the

1 monograph. Agreed?

2 A Would you repeat your question?

3 Q Sure. Where there is a USP monograph,
4 any drug product marketed in the United States must
5 meet the requirements and specifications of that
6 monograph?

7 A USP drug is the minimum requirement
8 that is required, absolute minimum. Manufacturers
9 are required to go above and beyond those
10 requirements.

11 Q Are they required to meet -- where a
12 monograph exists and applies, are manufacturers
13 required to meet their specifications of the
14 monograph?

15 A You spoke too fast. You got cut out.
16 Could you repeat?

17 Q I'll try. Where there is a USP
18 monograph that applies to a drug product are
19 manufacturers required to meet those specifications
20 and criteria in the monograph?

21 MR. NIGH: Objection. Asked and
22 answered.

23 A I answered that question already. USP
24 monograph is the minimum standards and manufacturers
25 are required to go above and beyond that.

1 Q Can you cite me an authority for the
2 proposition that you just stated, that the USP
3 monograph is a minimum standard? Where is that
4 specified anywhere in the public literature?

5 A I can't put my fingers on it right
6 now, but I can look it up for you and show you.

7 Q Well, we'll take multiple breaks
8 during this day and so I'd like you to find me --

9 A I will.

10 Q Let me finish, please. Can I finish,
11 please?

12 A Absolutely.

13 Q Sir, this is really difficult if we
14 talk over one another. I'll do my best not to talk
15 over you, but please let me finish my statement and
16 my question.

17 I'd like you to cite for me the authority for
18 that novel proposition that you just offered, because
19 I've not seen it.

20 A I will.

21 MR. NIGH: Hold on. Hold on. Hold
22 on. Form objection and now I would object to
23 whatever exercise there is that is supposed to do
24 something during the breaks while he's trying to
25 take restroom breaks. We are going far outside the

1 scope of his opinion and he has authority in his
2 expert report if you want to read his certification.

3 A Sir, can I respond to that question?
4 I think that I can refer you to USP's website and
5 under, basically, overview, USP monograph basically
6 articulates that there is a minimum quality
7 standards and the companies have to go above and
8 beyond that.

9 Q So I will find that on USP website?

10 A You should able to find that on USP
11 website, usp.com. Go to about USP and you should be
12 able to find that.

13 Q Will I find that requirement posted
14 anywhere else?

15 A I don't know. I'm sure there are. If
16 you Google it, you will find it.

17 Q Is there any requirement anywhere in
18 the USP mandating that a generic equivalent product
19 match or mirror the impurity profile of the RLD?

20 MR. NIGH: Form objection.

21 A There is the regs -- first of all, USP
22 is not a regulatory body. USP is an independent
23 company. The regs are clear. There is the concept
24 of sameness, chemical equivalents, active
25 equivalents, impurity equivalents, and there is the

1 concept of bio equivalents, therapeutic equivalents.
2 I can't comment on a lot of those things because I
3 am not a physician, but those are all spelled out in
4 the regs and you can look that up.

5 Q Where is the requirement for what you
6 call chemical equivalent, where is that term used in
7 the Food, Drug, and Cosmetic Act or the regulations
8 of the FDA?

9 A It's cited in my report, sir.

10 Q No, it's not. You don't provide any
11 citation for what constitutes chemical equivalents
12 in your report.

13 MR. NIGH: Objection. Hold on. I
14 don't know if that was a question.

15 A I responded to your question.

16 Q Show me in your report --

17 A Look at my report.

18 Q Show me in your report where there is
19 a regulatory definition of what you just called
20 chemical equivalence. You can look at your -- take
21 your time. Look at your report and show me where
22 there is a definition of chemical equivalence either
23 in Food, Drug, and Cosmetic Act or regulations in
24 the FDA or in any guidance in the FDA, for that
25 matter.

1 A Okay. Hang on one second. I've got
2 to get the report from my desk.

3 THE VIDEOGRAPHER: Would you like to
4 go off the video record or would you like to stay
5 on?

6 MR. TRISCHLER: I don't care.

7 A Okay. I'm back. Sorry. I put this
8 on my computer. Basically, the generic drug
9 manufacturers have an ongoing federal duty of
10 sameness in their product and their reference is
11 reference No. 2. What that refers to is that the
12 identity of the active ingredients need to be
13 exactly the same. The chemical synthesis of the
14 actual ingredients need to be the same. And also,
15 this refers to the impurities that are present need
16 to be impurities that are either established by the
17 brand, established by the USP or impurities that are
18 established by the generic manufacturers; and those
19 impurities, if the generic is using exactly the
20 brand chemical procedure, if they are using the same
21 recipe with the same, basically, various ingredients
22 that they're using; different intermediates,
23 different reagents, if they are using the same, then
24 they should expect to have the same chemical
25 impurities.

1 If they are modifying the chemical procedure,
2 in which case in the case of your clients they are
3 modifying their brand's chemical procedure, then they
4 should expect a different chemical impurities. And
5 because they are modifying those chemical procedures
6 and the reagents, then they have an obligation to
7 identify those impurities and determine that they are
8 not genotoxic.

9 It's a very long winded question to my,
10 basically, one paragraph. It's No. 18 in my expert
11 report.

12 MR. TRISCHLER: Object and move to
13 strike as nonresponsive.

14 Q Do you remember what they question
15 was?

16 MR. NIGH: Hold on. This has already
17 been discussed that it's inappropriate during the
18 deposition. It's already been ruled on to object as
19 nonresponsive. The colloquies that you're giving,
20 Mr. Trischler, have been ruled on previously as
21 inappropriate.

22 You've also threatened sanctions.
23 That's also been ruled on as being inappropriate.
24 These are all the things that the defendants argued
25 that Mr. Slater was doing that was inappropriate and

1 now you're doing it yourself after Judge Menaski
2 ruled that all these issues are inappropriate.
3 We've got to put some brakes on this.

4 MR. TRISCHLER: Are you done with your
5 speech, Daniel? I just asked him.

6 MR. NIGH: No, no, no, no. You can't
7 ask him --

8 MR. TRISCHLER: All I am asking is if
9 he remember --

10 MR. NIGH: You can't move to strike.
11 It's inappropriate, and the combativeness with this
12 witness is completely inappropriate. It's not just
13 the speech. We can have a conversation with the
14 judge if we need to.

15 MR. TRISCHLER: Are you done?

16 MR. NIGH: No, I'm not done. I don't
17 think you're recognizing it. You're doing so many
18 inappropriate things. We have to not do this. You
19 can't badger this witness.

20 MR. TRISCHLER: If you need to call
21 the judge, go ahead. I welcome it.

22 MR. NIGH: Okay.

23 MR. TRISCHLER: I welcome it.

24 MR. NIGH: Are you going to keep doing
25 the things you're doing?

1 MR. TRISCHLER: Because I would love
2 the judge to read this transcript.

3 MR. NIGH: Do you have every intention
4 to keep threatening for sanctions? Do you have
5 every intention to keep moving to strike as
6 nonresponsive, because if you do, then we might as
7 well call the judge now, because he's already ruled
8 that that's inappropriate.

9 MR. TRISCHLER: I have already
10 intention of asking relevant questions and I'm
11 hoping to get some responsive answers to those
12 questions.

13 MR. NIGH: Okay. Well, I hope that
14 you stop moving to strike as nonresponsive and
15 threatening sanctions.

16 MR. TRISCHLER: If you want to call
17 the judge, I'd welcome it, because I would love for
18 him to have the opportunity to read this transcript.

19 A Please repeat your question.

20 Q You used the term "chemical
21 equivalents" and suggested that generic
22 manufacturers have an obligation to establish
23 chemical equivalents and my question to you, sir,
24 was where in the Food, Drug, and Cosmetic Act or the
25 regulations of the FDA is the term "chemical

1 equivalents" anywhere defined and where would that
2 requirement be established? That was what led you
3 to look at your report. That's the question that
4 I'm looking for an answer to.

5 A Okay. Let me go back to my report
6 again, okay. So I'm going to read back from my
7 report, okay. Generic drug manufacturers have an
8 ongoing federal duty of sameness in their product,
9 reference No. 2. The generic manufacturers must
10 demonstrate that their active ingredients are -- and
11 have identical strength quality, purity -- I
12 underlined that purity -- and potency and were
13 applicable other characteristics as the reference
14 listed drug.

15 (Clarification requested by the
16 reporter.)

17 A I will repeat. Generic drug
18 manufacturers have an ongoing federal duty of
19 sameness, meaning equivalence, in their products.
20 The generic manufacturers must demonstrate that
21 their active ingredients -- in this case active
22 compounds, the compound that's responsible for its
23 therapeutic potential -- are the same as reference
24 listed drug. "Same" here, Mr. Trischler, means
25 identical; identical chemical structure, identical

1 molecular weight, identical to every sense of
2 chemical sense. They should have same strength,
3 same quality, purity.

4 Purity here refers to the chemical purity of
5 the drug and the impurity profiles of those drugs;
6 and both potency. And potency is really a function
7 of, you know, excipients and what excipients it's in
8 and whether it's going to be released properly.

9 So you get into a -- you know, I could talk
10 about this for a couple hours, but that's what that
11 is. And I'm referencing No. 2, No. 3, No. 4, these
12 are basically the regs that are there.

13 And the regs, as you well know, are vague
14 enough and that can be -- you know, they are really
15 the minimum standards. You know there is a concept
16 that they say CGMP. C talks about current good
17 manufacturing practices and "current" means the
18 highest technology, technologies, of today; and the
19 generic are responsible to living up to that standard
20 of the latest standards.

21 I hope -- that was a long answer to your
22 question. I hope that I answered it.

23 Q It was long. It was not an answer to
24 the question, but I'll ask it again.

25 A Well, you know, that's my answer. If

1 you want, I can repeat the same thing that I just
2 gave you.

3 Q If you could stop talking for a
4 minute, I'll try to ask another question. What you
5 read from was paragraph 18 of your report, correct?

6 A Correct.

7 Q In paragraph 18 the words "chemical
8 equivalent" never appear, do they?

9 A Chemical equivalents --

10 Q Do the words chemical equivalent
11 appear?

12 MR. NIGH: No, no, no, no, no, no, no,
13 no.

14 Mr. Trischler, he was clearly not
15 finished with his answer there. No, no, no. That
16 is completely inappropriate. You can finish your
17 answer, Dr. Najafi.

18 MR. TRISCHLER: He has to answer it
19 first and then he can --

20 MR. NIGH: No, he does not. Let him
21 answer the question. Let him answer the question.
22 That's completely inappropriate.

23 MR. TRISCHLER: Now you're saying he
24 can't answer the question?

25 MR. NIGH: You're interrupting the

1 witness over and over and over again. He was not
2 done and he was starting to answer your question.
3 He got two words out and you interrupted him; two
4 words out. The video record is very clear on this.

5 MR. TRISCHLER: You just said he
6 doesn't have to answer the question. That's what
7 you just said.

8 A No, I did not say he doesn't have to
9 answer the question. I said he doesn't have to
10 answer it in the way that you want him to answer it
11 at the very beginning of the answer.

12 MR. TRISCHLER: Let's try it again.

13 MR. NIGH: How about you ask the
14 question and don't interrupt him, please.

15 MR. TRISCHLER: Let's try again.

16 MR. NIGH: That's pretty
17 inappropriate.

18 BY MR. TRISCHLER:

19 Q Do the words "chemically equivalent"
20 appear anywhere in paragraph 18 of your report?

21 A The word "equivalence" doesn't need to
22 appear in No. 18. Sameness is chemical equivalence.

23 Q Is there a definition of chemical
24 equivalence in the Food, Drug, and Cosmetic Act?

25 A I don't know.

1 Q Is there a definition of chemical
2 equivalence in the regulations established by the
3 FDA?

4 A I don't know.

5 Q Is there a -- you used the term
6 "impurity equivalence." Is there a definition of
7 impurity equivalence under the Food, Drug, and
8 Cosmetic Act?

9 A The definition I just read, it's
10 the -- regs are clear the active ingredients need to
11 be the same. They need to be identical. The
12 quality, purity; you know, the identity of the drug
13 needs to be identical; potency, those are what
14 chemical equivalence is referring to. Perhaps I'm
15 not giving you the answer you like to hear, but
16 that's the answer.

17 Q Is impurity equivalence a defined term
18 under the Food, Drug, and Cosmetic Act?

19 A I gave you my answer, you know. You
20 have to have -- you know, the purity profile need to
21 have -- you either are following the brand procedure
22 and recipe, then you're going to end up with the
23 same impurity profile. If you're not following the
24 brand's procedure, you're going to end up with
25 different impurity profile. Those impurities can be

1 safe, can be harmful.

2 Q Sir, I didn't ask you any of that.
3 All I simply asked you is you used the term
4 "impurity equivalence" earlier in your testimony and
5 my question is the term impurity equivalence a
6 defined term under the Food, Drug, and Cosmetic Act?

7 A I have to -- you know, I can look that
8 up during the break and get back to you.

9 Q Do you know if the term impurity
10 equivalence is defined in the FDA regulations or FDA
11 guidance?

12 A Purity profile is the same. You know,
13 basically you have to have -- you know, I responded
14 to the question. You're either following the
15 brand's recipe and you get the same purity/impurity
16 profile and the same purity or you're not following
17 brand's procedure.

18 If you're not following brand's procedure
19 you're going to get a different impurity profile and
20 those impurity profiles could have genotoxic compound
21 in it and it could be non-genotoxic compound in it.

22 Q Not my question again, sir. My
23 question was simply do you know whether the term
24 that you used "impurity equivalence" is a term that
25 is defined in any FDA guidance document or FDA

1 regulations?

2 A It may --

3 MR. NIGH: Hold on. Form objection.
4 Just give a little bit of time between his question
5 and your answer, because I may have an objection,
6 form objection. You can answer.

7 A It may or may not.

8 Q Does FDA ever establish a requirement
9 that a drug manufacturer identify all impurities in
10 its drug label?

11 A Would you repeat your question?

12 Q Is there any FDA requirement for a
13 drug manufacturer to identify all impurities in its
14 drug label?

15 A There is a requirement that the
16 manufacturers identify all impurities that are
17 greater than certain percentage, and also there is a
18 requirement that the manufacturers identify any
19 potential genotoxic impurities. And typically those
20 are considered impurities of concern because of
21 their genotoxicity and those impurities are
22 predetermined or pre -- sort of predicted by the
23 expert chemist at the manufacturers based on certain
24 ingredients and based on certain chemical structures
25 that may be used.

1 Q You know what I mean by labeling?

2 A Please define it.

3 Q Labeling is a defined term under the
4 Food, Drug, and Cosmetic Act. Are you familiar with
5 the FDA definition of the term?

6 A Why don't you give me the FDA
7 definition.

8 Q I don't have it in front of me, but
9 for purposes of today I'm talking about the full
10 prescribing information provided to prescribers and
11 patients when their drug is dispensed. Okay?

12 A Right.

13 Q Do manufacturers identify impurities
14 in their FDA-approved labeling?

15 A They do. Manufacturers do identify
16 impurities --

17 Q Okay.

18 A -- in their drug.

19 Q As part of your work in this case, did
20 you review the Diovan labeling?

21 A No, I haven't.

22 Q Have you reviewed the Exforge
23 labeling?

24 A No, I haven't.

25 Q I think I sent some potential exhibits

1 ahead of time to the court reporter that we
2 premarked. I think I premarked Exhibit 13 as a
3 Diovan label.

4 A I was told -- I got a piece of mail
5 here. I was told not to open it until you guys
6 instruct me. Is that the one you want me to open
7 it?

8 Q No, I didn't ask you to open anything.

9 A Okay. You want me to open it?

10 Q No. I have no idea what you're
11 talking about. I didn't ask you to do anything.

12 MS. HILTON: Just for the record,
13 Clem, this was something that John Giselson and the
14 Aurobindo counsel had sent to Dr. Najafi and
15 instructed him not to open it. So Dr. Najafi, I
16 think, continue to keep that box unopened until
17 Mr. Giselson and the lawyers for Aurobindo question
18 you.

19 BY MR. TRISCHLER:

20 Q What we marked as Exhibit 13 is a copy
21 of the FDA approved labeling for Diovan.

22 A Okay.

23 Q Have you ever seen this before, sir?

24 A Could you make it bigger?

25 THE VIDEOGRAPHER: Sir, we just lost

1 your video feed.

2 MR. NIGH: Is this document going to
3 also be disclosed, because he can look at the full
4 label and I don't see it here yet in the share file.

5 MR. TRISCHLER: Frank -- hold on a
6 second. I'm talking to Frank Stoy from my office
7 who I also think is listening in. Frank, why don't
8 you put in the chat all the things that we
9 premarked.

10 A I can't see this. I need to print
11 this. So if you could email it to me, Daniel or
12 Rosemarie, that would be great. I can print it so I
13 can look at it. I can't read it.

14 MR. STOY: I could try to draw up
15 these documents in the chat as we use it. There is
16 also a share file link that I think Layne just put
17 in the chat where, Dr. Najafi, you should be able to
18 download the exhibits as they're marked.

19 THE WITNESS: Great.

20 BY MR. TRISCHLER:

21 Q So you can't see this, is that what
22 you're telling me?

23 A I can't see it, no. I have a -- it's
24 very small on my screen.

25 Q Well, then I guess --

1 A What are you referring to?

2 Q Well, I guess -- hold on. I guess we
3 need to take a break until you can see it.

4 THE VIDEOGRAPHER: Going off the
5 record, yes?

6 MR. TRISCHLER: Yes.

7 THE VIDEOGRAPHER: The time is 9:58.
8 This concludes Media 1.

9 (A recess was taken.)

10 (After the recess the following
11 occurred:)

12 THE VIDEOGRAPHER: The time is now
13 10:14. We are back on the video record. This
14 begins Media 2. And counsel, would you like me to
15 put the document that was on the screen up again?

16 MR. TRISCHLER: Yes, please.

17 BY MR. TRISCHLER:

18 Q Doctor, earlier we had talked about
19 the definition of "adulterated" under the Food, Drug
20 and Cosmetic Act. Would you agree with me that the
21 term "misbranded" is also defined under the statute?

22 MR. NIGH: Objection. Scope.

23 A Would you repeat your question?

24 Q Is the term "misbranded" defined in
25 the Food, Drug, and Cosmetic Act?

1 MR. NIGH: Objection to form.

2 A Yes, I believe it is defined.

3 Q And under the Food, Drug, and Cosmetic
4 Act a drug is deemed misbranded when its labeling
5 proves to be false or misleading. Can we agree on
6 that definition?

7 MR. NIGH: Objection. Scope.

8 A I agree that a misbranded drug
9 contains something that shouldn't be there.

10 Q Is that your definition or are you
11 suggesting that's the definition provided in the
12 Food, Drug, and Cosmetic Act?

13 MR. NIGH: Objection. Form.

14 A A misbranded drug is a drug that has
15 false or misleading label.

16 Q Okay. Thank you. So now we are
17 looking at the labeling for Diovan. I have marked
18 it as Exhibit 13. Are you now able to see it?

19 A Yes. I have it on my second monitor
20 here so I can actually see it. I am going to be
21 looking at my own version, but I have it. I am
22 looking at the same area.

23 Q All right. And can you go through
24 this -- the label that we marked as Exhibit No. 13
25 and tell me where Novartis discloses the impurities

1 in its Diovan product?

2 A Okay. Let me look.

3 MR. NIGH: Objection. Scope.

4 A So Novartis does not mention this
5 particular genotoxic impurities, because their
6 product didn't have any.

7 Q That wasn't my question. My question
8 was where do they list any impurities.

9 MR. NIGH: Form objection. Scope.

10 A This is not the place where they would
11 list their impurities.

12 Q Is there any requirement that
13 impurities -- that a drug manufacturer list
14 impurities in its label, FDA labeling?

15 MR. NIGH: Objection. Scope.

16 A I don't think there is any
17 requirement, per se, to list it. You know, if
18 you're looking at this label, you know, the only
19 thing you see is the active compound.

20 Q And that's my question, sir. Does any
21 drug manufacturer list or identify impurities in its
22 labeling?

23 MR. NIGH: Objection. Scope.

24 A I don't believe they do, but they need
25 to file it with the FDA. They need to let FDA know.

1 They need to disclose it on their batch record.
2 They need to identify it, all their degradation
3 products, and disclose it to the FDA in their
4 filing.

5 Q In their -- sorry. I thought you were
6 finished. Well, that's true in part, but isn't it
7 also true that all -- that there is an allowance for
8 unknown and unidentified impurities in every drug
9 product made and sold in America?

10 MR. NIGH: Was that a question?

11 MR. TRISCHLER: Yes, sir.

12 MR. NIGH: Objection. Scope.

13 A What was your question?

14 Q I said isn't it true that there is an
15 allowance for unknown impurities in every drug
16 product?

17 MR. NIGH: Objection. Scope.

18 A There is an allowance for unknown
19 impurities for every drug, provided they are not
20 genotoxic.

21 Q And prior to June of 2018, can we
22 agree that there was no requirement established by
23 the FDA or specified in USP for nitrosamine-specific
24 testing?

25 MR. NIGH: Objection. Scope.

1 Q Are you referring to particular
2 valsartan drug?

3 A No, I'm talking about any drug. I
4 said prior to June of 20-- 18, are you aware of any
5 requirement that was established by the FDA or
6 specified in USP that required nitrosamine-specific
7 impurity testing.

8 MR. NIGH: Objection. Scope.

9 A So my answer is genotoxic compounds
10 need to be identified per the ICH guideline M7, and
11 I refer you to that. They need to be identified and
12 they need to be reported and they need to be
13 controlled and managed and, you know, the whole
14 nine yards. And yes, they would have to be -- they
15 would have to be measured and by various
16 instrumentation: GC, GCMS, LCMS, they need to know
17 the amount; and there was a limit on the amount
18 allowable for various impurities genotoxic
19 impurities, I should say.

20 UNIDENTIFIED SPEAKER: Excuse me,
21 counsel. Are you in need of another court reporter
22 or are you all set, Michelle? I was just told to
23 join the meeting.

24 (Off the record.)

25 Q Do you know what the acceptance

1 criteria was for impurities under the valsartan USP
2 monograph in the summer of 2018?

3 MR. NIGH: Objection. Form.

4 Q The acceptance criteria was to produce
5 the active compound and have impurities that are
6 safe, that are inert and have a safe drug. That was
7 the requirement, and there were impurities that were
8 listed that could potentially be formed and those
9 impurities are typically impurities that the brand
10 discloses to the USP or USP also, you know, acquires
11 it through their own research.

12 MR. TRISCHLER: Can you put up what
13 was premarked as Exhibit 17, please.

14 A Okay.

15 Q Have you seen this document before,
16 sir?

17 A Hang on a second. Let me -- this is
18 you is -- yes I have.

19 Q What is it?

20 A It's a USP, you know, monograph for
21 the -- basically, limits of different impurities and
22 different -- you know, the acceptance criteria from
23 USP's point of view.

24 Q And what's the acceptance criteria for
25 impurities under the USP standards as set forth in

1 Exhibit 17?

2 MR. NIGH: Objection. Scope.

3 A The acceptance criteria is to have,
4 you know, basically each total -- each individual
5 impurities not basically greater than .2 percent or
6 not important .2 or .4, various impurities that are
7 listed, and that would be the accepted criteria.

8 Q If you go to the next page of
9 Exhibit 17, in particular Table 1, it lists the
10 specification and acceptance criteria for unknown
11 impurities is 0.1 percent, correct?

12 MR. NIGH: Objection. Scope.

13 A Let me. Are you -- okay. Thank you
14 for making it bigger. So, yeah. As you can see
15 from this impurity profile, there is no genotoxic
16 impurity mentioned here.

17 Q I didn't ask you that, sir. I said,
18 what's the acceptance -- was the criteria in the USP
19 monograph for unknown impurities 0.1 percent.
20 That's the only question I asked.

21 MR. NIGH: Form objection. His answer
22 was responsive and I object to the colloquy. You
23 could answer.

24 A The acceptance criteria presupposes
25 that the compound in question has no genotoxic

1 compound such as NDMA or NDEA, presupposes.

2 Q Where does it say that in the USP
3 monograph?

4 A You don't see that on the screen. If
5 it was part of the impurity profile, it would have
6 been mentioned. Since it's not, it means it
7 shouldn't have any.

8 Q Today in 2021 what does the USP for
9 valsartan provide as to the impurity acceptance
10 criteria?

11 MR. NIGH: Objection. Scope.

12 A I haven't looked at the latest -- I
13 don't have access to that document but, you know, it
14 presupposes there is no genotoxic compound in
15 valsartan.

16 Q I'm puzzled by that, sir. Where is it
17 written anywhere in regulations, guidance or USP
18 acceptance criteria that these numbers presuppose no
19 genotoxic impurities; does anyone say that other
20 than Ron Najafi?

21 MR. NIGH: Object to the colloquy and
22 object to scope.

23 MR. TRISCHLER: There was no colloquy.
24 That was a question.

25 MR. NIGH: No, but beginning part of

1 that question started out with, "I'm puzzled." That
2 is a colloquy.

3 Q So this -- I will ask it again, sir.
4 This idea that these acceptance criteria presuppose
5 that there is no genotoxic impurities, where is that
6 coming from?

7 MR. NIGH: Objection.

8 Q Where --

9 MR. NIGH: Form objection.

10 Q Where is that?

11 MR. NIGH: Sorry. Scope.

12 A I refer you to USP website and
13 specifically there is a specific mention that for
14 impurities known that are suspected carcinogen that
15 are toxic, that are genotoxic, a quantitation and
16 detection limit shall be established. This is USP.
17 It is ICH guideline, ICH M7. It's FDA. You know,
18 if you want me, I can specifically cite you page and
19 the language during the break.

20 Q We don't have to. I would like that,
21 but we don't have to do it right now, because during
22 the last break I did some homework and I would ask
23 you to take a look at Exhibit 27. This is the USP
24 website you were telling me about, right?

25 A Right.

1 MR. NIGH: Objection to the colloquy.

2 Q And you said this is the site where I
3 can go to where there is going to be a statement and
4 public pronouncement that the USP specifications are
5 minimum standards, so look at Exhibit 27 and tell me
6 where it says that, sir.

7 MR. NIGH: Form objection. Outside
8 the scope. Mischaracterizes his testimony. You can
9 answer.

10 A I am not sure what you found on USP
11 website, if you found the right page, but I will
12 point that to you later.

13 Q I'm asking you to take a look at
14 Exhibit 27 and tell me if there is anything on
15 Exhibit 27 that suggests that the USP monographs
16 specifications are minimum standards.

17 A So, specifically monograph articulates
18 the quality expectation for medicines, including for
19 its identity, strength and performance. They are
20 also described a test to validate that in medicine
21 that its ingredients meet these criteria and
22 basically, I would have to do my own search to show
23 you that specific language. I'm not sure if you
24 have it in the documents you gave to me.

25 Q Exhibit 27 is a multipage document.

1 Do you want to look at the whole thing and see if
2 there's anything in there to suggest that USP
3 requirements are minimum standards?

4 A If you give me a second, I will look
5 it up for you.

6 Q Sure. Let's go off the record.

7 A Let's go off line.

8 MR. NIGH: Hold on. What are you
9 looking up at this point, Dr. Najafi, the exhibit?
10 You're looking at the exhibit or you're looking it
11 up online?

12 THE WITNESS: No. I want to go online
13 and look up something for him.

14 THE VIDEOGRAPHER: Are we all okay to
15 go off the record?

16 MR. TRISCHLER: Yes.

17 MR. NIGH: No. Do you want him to go
18 online and look this up for you, Mr. Trischler?

19 MR. TRISCHLER: The witness said he
20 wants to, so let's go off the record and we will
21 come back when he's ready.

22 THE VIDEOGRAPHER: The time is 10:32.
23 We are going off the video record.

24 (A recess was taken.)

25 (After the recess the following

1 occurred:)

2 THE VIDEOGRAPHER: The time is 10:46.

3 We are back on the video record. You may proceed.

4 BY MR. TRISCHLER:

5 Q Okay. We just took a break. Doctor,
6 you said that you wanted to take some time to review
7 some material. Have you had the chance to do that?

8 A Okay.

9 Q Have you had the chance to look at
10 whatever it was?

11 A Yes, I did. I did.

12 Q Hold on. That's the only question I
13 asked you right now. Did you talk to anyone while
14 we were on that break?

15 A No, I didn't.

16 Q You reviewed while we were on that
17 break?

18 A Yes.

19 MR. NIGH: It wasn't really a break
20 for Dr. Najafi.

21 Q What did we review at the time we went
22 off the record at your request?

23 A I looked at the USP website.

24 Q Okay. And did you find anything on
25 the USP website suggesting that the USP monographs

1 were minimum standards?

2 A So I looked at exact same page that
3 you're looking at, which is USP.org. It's about USP
4 public policy overview of monograph.

5 Q Did you find anything on that website
6 that we marked the pages of which we marked
7 Exhibit 27 that indicate the USP monographs are
8 minimum standards?

9 MR. NIGH: Form objection. That
10 document is just one small part of the entire
11 USP.org. You can see the site map which has much
12 more than this little snippet from the website.

13 MR. TRISCHLER: Is that a proper
14 objection?

15 MR. NIGH: It actually is, because you
16 misrepresented the document, so absolutely it is.

17 MR. TRISCHLER: You know better.

18 MR. NIGH: No. You misrepresented the
19 document in your question just now.

20 Q Sir, I'm just asking you to tell me
21 where it is published that USP monographs are
22 minimum standards. You made that representation.
23 Where is it published?

24 A Yes. So I would like to point you to
25 No. 1 where it says (1) monograph in your exhibit.

1 Monograph articulates the quality expectations,
2 quality expectations to anybody familiar with the
3 art; art of synthesis and manufacturing. It means
4 minimum expectation. That's my understanding and
5 that's my pure understanding.

6 Those quality expectations, it's like, you
7 know, just like the bar that you have to have, you
8 know, and that's a starting point for a medicine
9 including for its identity, strength, purity,
10 performance. They also describe the tests to
11 validate and so forth and so on, which is all -- you
12 can read it as well. That's the minimum standard.

13 Q And so if we go back to the monograph
14 itself which we had previously marked, I think, as
15 Exhibit 17, you remember the table told us that
16 under that -- it is the next page. Thank you.

17 The table told us that the acceptance criteria
18 for unknown impurities was 0.1 percent, right?

19 A Right.

20 Q And 0.1 percent, that translates to
21 about 1,000 parts per million, right?

22 A Right.

23 Q And if we're talking about a 320
24 milligram tablet and we wanted to convert that to
25 nanograms, that would be about 320,000 nanograms,

1 right?

2 A Yes.

3 MR. NIGH: Objection. Scope.

4 Q So, according to USP, whether it's
5 standards or minimum, maximum or something in
6 between, it's acceptable to have a drug product with
7 unknown impurities of as high as 320 nanograms in a
8 320-milligram tablet, right?

9 MR. NIGH: Objection. Scope.

10 A USP also refers you to ICH guidelines
11 and genotoxic guidelines, and those genotoxic
12 compounds could be as low as, you know, zero.

13 Q But it could be as high as 320,000
14 nanograms?

15 A Could be as high as that level, but
16 the drug would not probably get approved.

17 Q Well, it would meet USP acceptance
18 criteria, right?

19 A No, it wouldn't.

20 Q An unknown impurity -- we just went
21 through the table. An unknown impurity in a
22 320-milligram drug product can be as high as 320,000
23 nanograms, right?

24 A Unknown impurities that are not
25 genotoxic can be as high as, you know, 300,000

1 nanograms. If they are genotoxic, no.

2 Q I am going to switch gears for a
3 minute.

4 A And you can refer you to my reference
5 on ICH guideline M7.

6 Q I didn't even ask you a question.

7 A It's part of the previous question.

8 Q You told me at the beginning of this
9 deposition that you'd been retained in the valsartan
10 MDL to offer expert testimony right?

11 A Yes.

12 Q Do you remember when you were first
13 retained in the valsartan matters?

14 A Repeat your question, please.

15 Q Do you remember when you were first
16 retained in the valsartan matters?

17 A I think I was retained sometime in
18 2019; October, maybe September, October 2019.

19 Q Can you identify the plaintiff's
20 lawyer or lawyers who retained you?

21 A Yes.

22 Q Can you identify them?

23 A They're on the phone. They're on the
24 Zoom.

25 Q Well, I'd like you to tell me their

1 names, please.

2 A Daniel, Rosemarie and Brad.

3 Q Daniel Nigh -- for the record, Daniel
4 Nigh, Rosemarie -- what is Rosemaries' last name?

5 A Bogdan.

6 Q And who is the third person you
7 mentioned?

8 A Brad Vaughn.

9 Q I'm sorry. Did you say Vaughn?

10 A Yes. It's the firm Pendley Bovin &
11 Hoffman, I think, or --

12 Q All right. Have you also been
13 retained by plaintiff's counsel as a consultant in
14 the ranitidine MDL?

15 MR. NIGH: Hold on. I am going to
16 instruct him not to answer.

17 MR. TRISCHLER: Can I ask on what
18 basis?

19 MR. NIGH: Actually, we have disclosed
20 an opinion, so you can ask him. Go ahead.

21 Q Have you also been retained as a
22 plaintiff's consultant in the ranitidine MDL?

23 A I have been retained as a consultant
24 in the ranitidine matter.

25 Q And in this litigation, the valsartan

1 cases, do you understand that claims have been
2 brought against -- well, strike that.

3 Let me ask you this first: In the ranitidine
4 litigation, do you understand that claims have been
5 brought against brand and generic manufacturers based
6 on the presence of nitrosamines in
7 ranitidine-containing products?

8 A Could you repeat your question?

9 Q Sure. In connection with your work in
10 the ranitidine litigation, I'm simply asking you if
11 you have an understanding that in that lawsuit there
12 have been claims brought against both brand and
13 generic drug manufacturers based on the presence of
14 nitrosamines in drugs made by both brand
15 manufacturers and generic.

16 A I believe so.

17 Q Do you know how many drug
18 manufacturers and drug suppliers have been sued by
19 plaintiffs in the ranitidine MDL stating their
20 products contain nitrosamines?

21 A There are many, many. I can't tell
22 you.

23 Q Is the number more than 75?

24 A I don't think so.

25 Q More than 65?

1 A I don't think so.

2 Q More than 50?

3 A I don't think so.

4 Q Can you give me an estimate of how
5 many drug manufacturers and drug suppliers you
6 understand to be part of that case?

7 A Probably a dozen.

8 Q Do you know how many drug
9 manufacturers and drug suppliers are part of this
10 case, the valsartan MDL?

11 A I don't, perhaps a dozen.

12 Q In addition to the ranitidine MDL and
13 this lawsuit, is it true you're also working for
14 plaintiffs' lawyers in the metformin MDL?

15 MR. NIGH: Form objection. I am going
16 to instruct him not to answer.

17 MR. TRISCHLER: What's the basis,
18 Daniel, just so I have it on the record?

19 MR. NIGH: If he is a consulting
20 witness, there is no opinion that's been disclosed
21 of metformin.

22 MR. TRISCHLER: Well, I don't know.
23 I'm asking. Are you suggesting he's not a disclosed
24 expert in that case?

25 MR. NIGH: There's been no experts

1 disclosed in the metformin litigation.

2 Q Aside from the valsartan MDL and the
3 ranitidine MDL, are there any nitrosamine litigation
4 matters that you're working on where you have been
5 retained to offer expert testimony?

6 MR. NIGH: And I would instruct that
7 if you were working on any other matters where your
8 expert opinion hasn't been disclosed, that you not
9 answer that question, because it's privileged.

10 Q Can you answer that question, Doctor?

11 MR. NIGH: Can you ask the question,
12 any other litigations where his expert opinion has
13 been disclosed?

14 MR. TRISCHLER: I thought that was the
15 question I did ask. Do you want me to ask it again?

16 MR. NIGH: No, you actually didn't ask
17 that way, but if you ask that way, then we don't
18 have to worry about the privilege objection.

19 Q Other than ranitidine and valsartan,
20 have you been retained by plaintiffs in other
21 litigation where your opinions have been disclosed
22 to provide testimony on matters relating to
23 nitrosamines?

24 A So we are a contract lab and, you
25 know, less than 10 percent of our business comes

1 from litigation support but, yes, we have been
2 retained by other firms regarding nitrosamines.

3 Q And what other firms would that be?

4 MR. NIGH: Again, was there an opinion
5 disclosed in any other litigation other than
6 ranitidine and valsartan, any expert reports?
7 Otherwise, this is privileged material and I would
8 instruct you not to answer.

9 MR. TRISCHLER: I'm just trying to ask
10 a predicate question, whether there are any others.

11 MR. NIGH: He just said no. I don't
12 know if you heard him.

13 MR. TRISCHLER: I did not.

14 A I did not disclose any expert opinion
15 on any other matters.

16 Q Except ranitidine and valsartan,
17 that's your testimony?

18 A Valsartan we have not disclosed any
19 expert opinion either. We have not finalized our
20 expert opinion as of yet.

21 Q Well, that's news to me, because I
22 thought you did file a declaration that brings us
23 here today that contains some opinions and that's
24 what we're here to talk about.

25 In any event, I think what you're suggesting

1 to me is that you may have valsartan at a later date
2 and you may have other reports and other opinions; is
3 that what you're telling me?

4 A That's correct.

5 Q My only question -- only thing I am
6 trying to get to the bottom of is whether there is
7 any other litigation matters involving nitrosamines
8 that you have been involved in where you've
9 disclosed an expert opinion other than ranitidine
10 and valsartan?

11 A No.

12 Q The company that you own and operate,
13 as I understand it, is called Najafi Pharma Inc; is
14 that right?

15 A Najafi Pharma Inc.

16 Q Najafi Pharma. Sorry about that.

17 A Same as my last name.

18 Q Yes, and Najafi Pharma does businesses
19 as Emery Pharma?

20 A Yes, that's correct.

21 Q Is Najafi Pharma Inc. a corporation?

22 A Yes, that's correct.

23 Q Is it publicly or privately held?

24 A It's a privately held corporation.

25 Q Who are the shareholders of that

1 corporation?

2 A My wife and me.

3 Q How much of the stock do you own?

4 A Fifty-fifty.

5 Q I presume your wife then owns the
6 other 50 percent?

7 A That's correct.

8 Q And what is her name?

9 A Kelly Faranghi.

10 Q Do you mind spelling that for my
11 benefit?

12 A Sure. It's F as in Frank
13 A-R-H-A-N-G-I -- G-H-I, and first name K-E-L-L-Y.

14 Q Since you and Kelly are the sole
15 shareholders of Najafi Pharma Inc, I assume, then,
16 that all revenues generated after expenses go to you
17 and your wife?

18 A That's correct.

19 Q In connection with your work as a
20 litigation consultant in nitrosamine litigation, are
21 the fees that you generate and the income that you
22 receive paid to you through the company or is this
23 litigation work something that you do independent of
24 Emery Pharma?

25 A No, it's paid through the company.

1 Q Can you tell us what total revenues
2 have been generated by Emery Pharma by your work as
3 a paid consultant for plaintiffs in nitrosamine
4 litigation?

5 A I don't have the exact number, but
6 it's around 200.

7 MR. NIGH: No, no, no. Sorry. Sorry.
8 I would object. You can ask what percentage of his
9 revenue over the last few years, but you can't ask
10 total revenue numbers.

11 Q Who would --

12 MR. NIGH: If you want to ask for this
13 litigation, that's fair, but you can't ask for all
14 litigations.

15 A No, no.

16 MR. TRISCHLER: And that's not even a
17 proper instruction for you to give, so just keep
18 putting on the robe as well as acting as an
19 advocate. It's improper, but it doesn't appear that
20 you're ready to stop.

21 Q Did you -- who would have the
22 information about your company about what revenues
23 Emery Pharma has generated from work in nitrosamine
24 litigation?

25 MR. NIGH: Again, this goes outside

1 the scope of what is allowable. You can ask about
2 valsartan and the revenues for valsartan, but not
3 for all nitrosamine litigations.

4 MR. TRISCHLER: Only thing I've asked
5 for the name of a person at the company who would
6 have that information.

7 A I have that information.

8 Q So you know the exact dollar amount?
9 I thought you said a few minutes ago you didn't know
10 it.

11 A No, I didn't say that.

12 Q Let me ask about some of the records
13 that I received specific to your valsartan work.

14 MR. TRISCHLER: Can you display what I
15 premarked as Exhibit No. 2, please?

16 A Yes.

17 Q Exhibit No. 2 looks to be some form of
18 a retainer agreement. Do I understand that
19 correctly?

20 A That's correct.

21 Q And is this the retainer agreement
22 that confirms your engagement --

23 A That's correct.

24 Q You've got to let me finish the
25 question, sir; confirms your engagement as a

1 litigation consultant for the plaintiffs in the
2 valsartan litigation?

3 A That's right.

4 Q It looks like, if we go to page 4 of
5 this exhibit, it looks like it was signed in October
6 of 2019. Do I have that right?

7 A That's correct.

8 Q And somewhere in here I think you
9 requested or your company requested a retainer of
10 \$5,000; is that right?

11 A I guess so, yes.

12 Q Is that your usual retainer or would
13 that be something that was different for this case?

14 A It varies.

15 Q Was that retainer paid, if you know?

16 A Yes, it had.

17 Q And the retainer agreement says -- I
18 have to find the right spot, so bear with me.

19 A All right.

20 Q I'm looking at page 3, if you could
21 turn there. Thank you. There is a paragraph under
22 background and scope of work. Do you see that, sir?

23 A Yes, I do.

24 Q And it says you're being -- Hollis Law
25 is engaging Ron Najafi as a consultant expert

1 witness and Emery Pharma for laboratory activities
2 relating to valsartan NDMA, NDEA, NBMA and DMF.

3 A That's correct.

4 Q What is NBMA?

5 A That's another nitrosamine impurity.

6 Q Do you know what NBMA stands for?

7 A Not off the top of my head, but it
8 is -- it could be butyl nitrosol -- n-methyl butyl
9 nitrosamine. It could be n-methyl for amino, so I
10 have to check with my chemistry team what is part of
11 the proposal.

12 Q Is part of the proposal DMF; what is
13 DMF?

14 A DMF stands for dimethyl fumarate.

15 Q And the second part of that or second
16 paragraph under that background and scope section of
17 the retainer agreement says, "While not currently in
18 the scope of work, if any testing of valsartan pills
19 is ordered by clients in the future, such testing
20 will be performed under CGMP/GLP."

21 A Right.

22 Q Did I read that correctly?

23 A That's correct.

24 Q And the -- see, I'm pretty sure I know
25 what CGMP stands for. That's current good

1 manufacturing practices, right?

2 A Yes.

3 Q What does GLP stand for?

4 A Good laboratory practices.

5 Q And CGMP and GLP guidelines that you
6 reference in this retainer guidelines specific --
7 that would have been developed specific by you for
8 your lab or are you referencing or intending to
9 reference general standards for GMP and GLP?

10 A So Emery Pharma is an FDA-registered,
11 FDA inspected GLP, GMP compliant laboratory and we
12 do perform work that is under GLP, GMP to those
13 standards. It means that you maintain good
14 laboratory notebooks. It means that your
15 equipment -- that their products is going to be
16 tested. It's qualified. It's calibrated. So those
17 are some of the things that, you know, this sentence
18 effectively promises.

19 Q And I understand that. I guess my
20 question was, are the guidelines that you are
21 referring to in this retainer a guideline of general
22 applicability for all registered labs or are they
23 specifically developed for your lab?

24 A No, there are a lot of general labs
25 that contract labs could follow GLP, GMP; could be

1 compliant with GLP, GMP and maybe not compliant with
2 GLP, GMP and may do things under R&D condition, so
3 it really depends on the lab.

4 Q And who published the CGMP and GLP
5 guidelines that are referenced in your retainer
6 agreement?

7 A This particular -- are you referring
8 to this particular retainer agreement?

9 Q Well, yes, because that's the only
10 retainer agreement I have.

11 A I put it together.

12 Q I know you put it together.

13 A I have my signature on it.

14 Q You're not following me. Hold on.
15 You're not following my question, sir. My question
16 was who has published the guidelines that you make
17 reference to in this?

18 A The guidelines are set by the FDA, by
19 European medical authorities, by ICH.

20 Q And you go on to, in this retainer
21 agreement, state that if any testing of valsartan
22 pills is ordered in the future, such testing is
23 going to be performed under the guidelines. Do you
24 see what I am referring to?

25 A Right.

1 Q Prior to the time that you entered
2 into this retainer agreement in October of 2019, had
3 your lab ever conducted any testing of
4 valsartan-containing medications produced by Mylan
5 Pharmaceuticals?

6 A The answer is we have conducted
7 valsartan testing prior to this retainer agreement.

8 Q And was the valsartan testing that you
9 conducted, was it using valsartan tablets produced
10 by Mylan?

11 A I don't recall.

12 Q Was the valsartan -- and right now I
13 am only asking you about testing you did prior to
14 entering this agreement. Was the valsartan lab
15 testing that was done at Emery prior to the entry of
16 this agreement, did it involve any valsartan
17 containing medications produced by ZHP?

18 A I do not recall.

19 Q Did it involve what I'll call the
20 pre-retainer testing, okay?

21 A Right.

22 Q Did any valsartan testing that you
23 made reference to that was conducted at the Emery
24 lab involve any other valsartan-containing
25 medications produced by Hetero?

1 A I do not recall and if I did, it would
2 be privileged. It would be under a different, you
3 know, agreement with another law firm.

4 Q Did any of the testing that you did
5 prior to this retainer agreement involve
6 Aurobindo-manufactured products?

7 A I do not recall. I don't know.

8 Q Do you recall if any of the
9 pre-retainer valsartan testing done at your
10 laboratory involved any valsartan-containing
11 medications produced by any of the defendants to
12 this litigation?

13 A I do not recall the manufacturer's
14 name that we tested prior to this agreement. It
15 could have been any one of those companies.

16 Q Since you entered into this retainer
17 agreement and became a consultant in this valsartan
18 litigation in October of 2019, have you ever
19 conducted any lab testing on any valsartan
20 medications produced by Mylan?

21 A I do not recall. We test valsartan.
22 We assign numbers to pills. We have very good chain
23 of custody. We typically -- the operators who do
24 the testing, they have no idea who is manufacturing
25 the pills. There simply there is an ID to it and

1 chain of custody and they get it tested, and I
2 honestly don't know. I don't pay attention to who
3 the manufacturers are.

4 Q So your lab has done valsartan testing
5 of valsartan medications since entering into this
6 retainer agreement, correct?

7 A We have done lots of valsartan testing
8 prior to this agreement and we've done more
9 valsartan testing post this agreement.

10 Q And if I understand your testimony --
11 I am going to get into the details of it more, but
12 if I understand your testimony so far, what you're
13 suggesting is that as you sit here today providing
14 testimony under oath, you're not able to tell us
15 whose valsartan product you tested in terms of who
16 the manufacturer was?

17 A No, I don't have that information.

18 Q Would there be records available in
19 your lab records that would tell you that?

20 A Yes, there would be records available
21 at our lab that would tell me exactly what the
22 manufacturers are.

23 Q When did your lab first start doing
24 valsartan testing?

25 A I think around maybe May of -- April,

1 May of 2019.

2 Q What was the reason that your lab
3 started to do valsartan testing in April or May of
4 2019?

5 A I think it was initiated primarily by
6 the recall of valsartan products.

7 Q And is it something that your lab did
8 on its own initially or were you retained by
9 somebody to do that testing in April and May of
10 2019?

11 A We were retained.

12 Q And who retained you in April or May
13 of 2019 to do that testing?

14 MR. NIGH: Again, if this is
15 privileged information and has nothing to do with
16 this case, then I would instruct you not to answer
17 and waive whoever else's privilege you have.

18 A It is confidential and privileged.

19 MR. TRISCHLER: Well, I think -- you
20 know, in fairness, I think I am entitled to know who
21 it was in order to determine whether there is any
22 claim of privilege.

23 A It was a law firm.

24 Q Was it a law firm representing a
25 plaintiff, representing a manufacturer, a drug

1 supplier; do you know?

2 A It was a law firm representing
3 plaintiffs.

4 Q Is that firm that retained you in
5 April or May of 2191 of the law firms that are
6 involved in the valsartan MDL?

7 A I don't know.

8 Q Do you know if the lawyer for the firm
9 that retained you is involved in the valsartan MDL?

10 A We do the testing. We know the
11 nitrosamine. We know the chemistry. We don't
12 really get involved with, you know, sort of the
13 legal aspects of what's going on.

14 Q I understand. My question was
15 simply -- and if you don't know you can tell me you
16 don't know, but my question --

17 A I don't know. I don't know, honestly.
18 They may be involved with MDL. They may not.

19 Q And so are you able to describe for me
20 what type of testing you were retained to do in
21 April or May of 2019?

22 MR. NIGH: Let me in for a second
23 here. I am going to object. I think all this
24 information is privileged. I appreciate, Clem,
25 Mr. Trischler, trying to understand who the parties

1 are and I think Dr. Najafi just doesn't know whether
2 or not they are related to MDL. I think we do know.
3 It has no bearing on any of plaintiff's counsel and
4 no relation to this MDL, but I don't think that he
5 knows that. Why you ask him sitting here today.

6 MR. TRISCHLER: I understand and I am
7 not trying to be unfair, Daniel. I'm just trying
8 to -- if we need to raise the issue, I'm trying to
9 understand some of the basic facts of what was done
10 and when so that -- and sort of making a record. I
11 assume if we get into it later, I don't think
12 there's any dispute that we ought to be entitled to
13 know the basic facts of what he did so we can argue
14 relevance and privilege to the Court, and that's all
15 I am really trying to do here.

16 I think the only question pending at
17 this point is are you able to describe the type of
18 testing that was done in April or May of 2019.

19 MR. NIGH: No, I think that that's
20 privileged.

21 BY MR. TRISCHLER:

22 Q Were reports of -- whatever testing
23 was done, were reports generated?

24 MR. NIGH: Again, privileged.

25 MR. TRISCHLER: Well, I didn't ask

1 what the reports disclosed, just whether reports
2 were generated.

3 MR. NIGH: Again, privileged.

4 MR. TRISCHLER: So you're instructing
5 him not to answer that question?

6 MR. NIGH: Yes.

7 BY MR. TRISCHLER:

8 Q Were there established lab protocols
9 that Emery had created pursuant to which the April,
10 May 2019 testing was conducted?

11 MR. NIGH: Again, privileged.

12 MR. TRISCHLER: See, Dan, I disagree
13 with you there. If there is an established protocol
14 that they have that's part of their everyday, work I
15 think I'm clearly entitled to that. I'm not asking
16 him the results of the testing, but just the
17 protocols that were followed. Those are lab
18 procedures. I don't think -- that's not privileged.

19 MR. NIGH: You know, for the
20 certification he doesn't rely on testing of the
21 valsartan pills at all whatsoever in any of his
22 testing that he has done, so it's outside the scope
23 and privileged.

24 MR. TRISCHLER: And I don't want to
25 argue relevancy or privilege with you right now. I

1 am just trying to understand the facts so that we
2 can seek the information later, but the fact that
3 he's not relying on it for whatever opinions he
4 intends to offer at this stage of the proceedings is
5 not determinative. For all we know there may be
6 information that undermines his opinions, but we
7 don't know until we have an opportunity to discover
8 it.

9 Again, the only question pending at
10 this point -- you've made your objections where you
11 think they are appropriate and I am not arguing any
12 of them, Dan. I am just asking you to reconsider
13 the objection to the question I just asked about
14 whether there are existing lab protocols pursuant to
15 which this work in 2019 was done. I don't think
16 that's privileged at all.

17 MR. NIGH: I think you asked that
18 question a little bit differently and I think he can
19 answer that question.

20 MR. TRISCHLER: Tell me how you think
21 it should be asked differently and I will accept
22 that.

23 MR. NIGH: No, no. I think you asked
24 it differently. My understanding is you're asking
25 do they have guidelines as to how this testing would

1 be conducted. That's different.

2 MR. TRISCHLER: Well, that was --

3 MS. HILTON: Not developed for the
4 testing, but do they have guidelines that were in
5 place or existing at the time of the testing.

6 MR. TRISCHLER: Yes. That's what I'm
7 looking for.

8 A So what's the question?

9 Q The question was at the time this
10 testing was done in April or May of 2019, did your
11 lab have existing protocols and guidelines in place
12 that would have governed that testing.

13 A We follow several guidelines, several
14 procedures from FDA on testing of, basically,
15 nitrosamines, and that's what we use. So it's
16 established testing guideline, you know, with the
17 full following the same guideline procedure
18 controls.

19 Q Do you have any information --
20 whatever the valsartan that was tested in April or
21 may of 2019, do you have any idea where it came
22 from?

23 MR. NIGH: I am going to object to
24 privilege and instruct him not to answer. Actually,
25 I think we have gone far beyond. I think we are

1 going to have to brief this at this point,
2 Mr. Trischler, because even his last answer
3 contained, you know, essentially privileged
4 information. Anything that has to do with testing
5 that has no nexus to this litigation is privileged.

6 MR. TRISCHLER: Okay. I disagree.
7 You've disclosed this witness as a testifying
8 expert. He's now indicated that he conducted
9 valsartan testing to ascertain nitrosamine levels.
10 He did it in 2019. He's been doing it on an ongoing
11 basis and the suggestion has nothing to do with this
12 litigation. I think it has no factual merit
13 whatsoever, no disrespect intended. So we obviously
14 have a disagreement, but if --

15 MR. NIGH: We do, and I am going to
16 instruct him not to answer any further. I would
17 just redirect to his opinion. It's simply not how
18 NDMA, how much products have NDMA. His opinion
19 boils down to valsartan-containing products that
20 contain NDMA OR NDEA but the generic equivalent of
21 Diovan or Exforge because they contained NDMA, NDEA.
22 It's as limited as to that. So whatever tests that
23 he's done in other litigations, there is no
24 relevancy stacked on top of the fact that it's
25 privileged. So I am going to instruct him not to

1 answer about any testing that he has done outside of
2 this litigation.

3 MR. TRISCHLER: Also your instruction
4 applies to what he described and what we have been
5 calling as the April/May 2019 testing. I think he's
6 also indicated they have been testing valsartan on
7 an ongoing basis.

8 MR. NIGH: That's correct, and my
9 instruction would apply equally to that testing that
10 has no basis in this MDL.

11 MR. TRISCHLER: So your position, just
12 so I'm clear and I don't have to belabor the record,
13 is that we can agree that the witness operates a
14 research lab that's done testing on
15 valsartan-containing medication for nitrosamine
16 content on a fairly consistent basis since April and
17 May of 2019, some of which may include
18 valsartan-containing medications produced by the
19 defendant in this litigation, some of which may
20 include valsartan containing medications produced by
21 manufacturers and suppliers that are not parties to
22 this litigation, but your instruction is a global
23 one that all of that testing is off limits,
24 according to the plaintiff and that the witness will
25 be instructed not to answer any questions at all

1 about it. Is that your position?

2 MR. NIGH: I think he's answered he
3 doesn't know which manufacturer, so that's been
4 established already right. Other than that, my
5 instruction would be no further testimony, and I
6 would instruct him not to answer about any further
7 testimony about testing that he has done, since none
8 of that testing was done for the MDL on behalf of
9 the MDL and has no nexus to the MDL. Actually, if
10 we need to brief it, we can.

11 MR. TRISCHLER: Right. I will just
12 say we disagree. I think it's clearly relevant and
13 probative, but we can save it for a future date. I
14 don't want to belabor the record on it, so let me
15 move on.

16 MR. NIGH: I understand.

17 BY MR. TRISCHLER:

18 Q You talked about or I was asking you
19 about your work in the valsartan MDL. In addition
20 to that retainer, I wanted to ask you about some
21 documents that I received. I received a few
22 invoices from your firm, Doctor, and I've had those
23 invoices marked Exhibits 3, 4, 5 and 6, okay.

24 MR. TRISCHLER: Can you put up -- I
25 guess we'll start with Exhibit 3.

1 A Okay.

2 Q It looks like Exhibit 3 is an invoice
3 that's dated August 2, 2001, correct?

4 A That's correct.

5 Q This that August invoice you've
6 submitted a bill for six hours of time for document
7 reviews that were apparently done in July of last
8 year; is that right?

9 A Right.

10 Q And then Exhibit 4 is dated
11 January 28, 2022; just last week, right?

12 A Right.

13 Q And there you billed, submitted an
14 invoice for two hours worth of time that you spent
15 back in October of last year, right?

16 A Not October, November.

17 Q Well, it says class certification
18 review October 25, 2021?

19 A Right. Right. Exactly.

20 Q So what does that mean, class
21 certification review October 25, 2021?

22 A So this is the -- pertains to my
23 expert report on the class certification primarily.

24 Q I wasn't sure. Is there some -- I
25 don't know what "class certification review" means.

1 What did you do over those hours?

2 A The expert report that you were
3 looking at earlier, essentially, review of
4 documents, review -- you know, putting that
5 together, putting the expert report together and
6 putting the package of citations and everything that
7 needs to be that you all have in your hands
8 together.

9 Q Okay. And then the other invoice that
10 I have is Exhibit 5. It's dated January 31, 2022,
11 which is just a few days ago, right?

12 A Right.

13 Q And you've got two more hours that you
14 billed for review of class certification final
15 declaration review in November -- on November 4,
16 2021, right?

17 A Right.

18 Q I guess you spent two hours reviewing
19 that declaration on that date?

20 A Right, but this is reviewing a lot of
21 the citations, reviewing the -- you know, just
22 preparing. This is just preparation for today's
23 call.

24 Q Okay. And then the final invoice that
25 I received is Exhibit 6. We marked that. It's

1 dated February 1, 2022, and you've got a bill for
2 about 15 hours of time?

3 A It's, again, reviewing for today's
4 call and refreshing my memory on the various
5 citations that I'm quoting and all of that.

6 Q Right. So it looks like you spent
7 about 15 hours --

8 A Right.

9 Q -- preparing for this deposition?

10 A Exactly.

11 Q And when you were preparing for this
12 deposition, who were you preparing with?

13 A Myself --

14 Q And --

15 A -- and I also spent some time with the
16 plaintiff's lawyer discussing the deposition.

17 Q And which lawyer would that be on the
18 plaintiff's side?

19 A Rosemarie, Daniel, Brad and Layne.

20 Q So I assume these invoices, then, that
21 we have that we marked as exhibits 3 through 6 would
22 accurately reflect the time that you spent and that
23 you devoted to this valsartan project since you were
24 retained in October of 2019, right?

25 A This is not all of them. This is

1 primarily just specific to this expert report that
2 we did.

3 Q Well, I am interested in all the time
4 and work and billing that you have submitted in
5 connection with your working in valsartan MDL. So
6 this is just a drop-in the bucket?

7 A This is a portion of the bills that we
8 have given. We haven't shared all the bills.

9 Q Why not?

10 MR. NIGH: That's a legal question.
11 We objected and provided the reasons for that
12 objection. His opinion here today is limited on his
13 class certification and not his liability on things.

14 Q So let me ask you about the
15 declaration itself. You have -- I marked the
16 declaration as Exhibit No. 1. Do you have a copy of
17 it there or do you need to have the --

18 A I have it.

19 Q You have it?

20 A Yes, I do.

21 Q All right. And so this is a
22 declaration that has your name and your signature
23 attached to it, correct?

24 A Correct.

25 Q And it's not on the letterhead of

1 Emery Pharma, is it?

2 A No, it's not.

3 Q It's not on your personal letterhead,
4 is it?

5 A No, it's not.

6 Q Was this something that you personally
7 prepared or was this prepared by the lawyers?

8 A No, I personally prepared the
9 document.

10 Q Every word of this is your words?

11 A Yes, it is.

12 Q No help from the lawyers?

13 A No help.

14 Q And as I read the declaration, it
15 appeared to me that there were two opinions
16 contained in this declaration. The first one was
17 that you suggest that NDMA and NDEA should not be
18 present in any drug, am I correct that in stating
19 that sort of opinion that you hold and you expressed
20 in this declaration?

21 A Please repeat your question. I lost
22 track.

23 Q Yeah. I was just trying to summarize
24 what I think your opinions are that are contained in
25 this declaration and I want to make sure I got it

1 correct. So what I was saying was --

2 A Yeah.

3 Q -- in this declaration --

4 A Yeah.

5 Q -- you state that NDMA and NDEA should
6 not be present in any drug. Is that an opinion that
7 you hold?

8 A NDMA and NDEA are carcinogenic
9 mutagenic compound that should not be present in any
10 drug period.

11 Q And then the second opinion that I saw
12 in this declaration was that you suggest that the
13 presence of a nitrosamine impurity in a generic drug
14 product renders that --

15 A Could you point to that? Your screen
16 is frozen.

17 Q Point to what, sir?

18 A Point to -- you're showing me a
19 document on this screen.

20 Q No, I wasn't. We can take the
21 document down.

22 A Okay.

23 Q You have the report in front of you.

24 A I thought you were quoting from my
25 declaration, but go ahead.

1 Q No.

2 A What's your question?

3 Q I am trying to ask you a question. In
4 your declaration do you offer the opinion that the
5 presence of any nitrosamine impurity in a generic
6 drug product renders that product not equivalent to
7 the reference listed drug?

8 A Absolutely.

9 Q And do you agree that those are the
10 opinions that you set forth in your declaration and
11 that you intend to offer in this matter?

12 A Absolutely.

13 Q Are there any others?

14 A No generic drug should contain any
15 mutagenic compound, particularly NDMA and NDEA and,
16 essentially, any nitroso compound. They are cohorts
17 of concerns and their limits should be zero.

18 Q And that was the first opinion that we
19 went over. Other than those two opinions, are there
20 any others that you intend to offer?

21 A I might have opinions to offer in my
22 full expert report which will be coming shortly, but
23 what you see for now is what I think I have, but I
24 will have other opinions as well.

25 Q I'm sure we will all wait with bated

1 breath for the next report, but at this time at this
2 state of litigation, those two opinions are the
3 stated opinions that you intend to offer; is that
4 right?

5 A Yes.

6 MR. TRISCHLER: Dan, can we take a
7 five minute comfort break?

8 MR. NIGH: Yes. Let's take ten
9 minutes.

10 THE VIDEOGRAPHER: The time is 11:41.
11 This concludes Media No. 2.

12 (A recess was taken.)

13 (After the recess the following
14 occurred:)

15 THE VIDEOGRAPHER: The time is now
16 12:03. This begins Media No. 3. You may proceed.

17 BY MR. TRISCHLER:

18 Q Doctor, allow me to cover a few
19 additional background issues with you, if I can. As
20 I understand it, your background and education is in
21 the field of chemistry, correct?

22 A That's correct.

23 Q I was provided with a copy of a CV.
24 I've marked it as Exhibit 7.

25 A Okay.

1 MR. TRISCHLER: Can someone put it up
2 for me, please. Can you go to the next page.

3 Q If you need more time, tell me and
4 continue, please.

5 A I am familiar with my CV.

6 Q All right. And is this a -- what we
7 marked as Exhibit 7 a true, correct and accurate
8 summary of your qualifications and credentials?

9 A That's correct.

10 Q In the copy of the CV that I received,
11 I did not see any list of publications. Do you
12 maintain a list of publications?

13 A It should be. It should be there.

14 Q Can you flip through? Maybe this is a
15 different one than what I had with the report.

16 A Maybe this is a different one.

17 Q Is that the end of the document there?

18 THE VIDEOGRAPHER: There are 13 pages.
19 Do you want me to keep flipping through or do you
20 want me to when you're ready for the next one?

21 MR. TRISCHLER: Yes. Keep flipping
22 through, because if it's more than five pages, then
23 it's different than one I have.

24 A Now you see the publication.

25 Q Yes. Okay. The copy that I was

1 looking at did not have that. All right. Thank
2 you.

3 A What is your question?

4 Q As far as you know, this version of
5 the CV we marked as Exhibit 7 is current, up to date
6 and accurate, right?

7 A Right, as long as you can show me
8 everything else, because it sounded like you were
9 missing some parts of it. I only see two
10 publications on your exhibit.

11 Q Well, we said we can flip through the
12 rest if you like. That's why I asked if you wanted
13 to.

14 A Yes, flip through it.

15 THE VIDEOGRAPHER: This is page 6,
16 Doctor. Just let me know when you're ready for the
17 next page.

18 THE WITNESS: Yes. Go ahead. Go
19 ahead. Yes. Uh-huh. Okay. Yes.

20 THE VIDEOGRAPHER: There's two more
21 pages.

22 A Okay. I think you have everything.

23 Q So we're good? In terms of what we
24 marked as Exhibit 7 is the up to date, current and
25 accurate summary of your qualifications, right?

1 A Correct.

2 Q Good. And what I remember reading is
3 that you obtained a bachelor's and master's in
4 organic chemistry from the University of San
5 Francisco, right?

6 A Correct.

7 Q And I think it was in 1998 you got
8 your PhD in organic chemistry from U.C. Davis?

9 A That's correct.

10 Q And after completing your PhD you went
11 to work as a research scientist for a few chemical
12 and pharmaceutical companies before starting your
13 own business around 1996?

14 A That's correct.

15 Q And the company that you started in
16 1996 was a company called CP Lab Safety; do I have
17 that right?

18 A That's correct.

19 MR. TRISCHLER: You could take the CV
20 down, sir.

21 Q How long did you run CP Lab Safety?

22 A Probably around two years, two or
23 three years.

24 Q Did CP Lab Safety develop or
25 manufacture drug products?

1 A No.

2 Q Did CP Labs hold any new drug
3 applications?

4 A No.

5 Q Did CP Labs hold any abbreviated drug
6 applications.

7 A No.

8 Q Did CP Labs hold any or were they
9 responsible for any drug master files?

10 A No.

11 Q While at CP Labs, were you or was your
12 company at all involved in the synthesis,
13 manufacture or testing of API for drug products?

14 A No.

15 Q At CP Labs did your company have any
16 role in the formulation, synthesis, manufacture,
17 production or testing of angio tensin receptor
18 blocker medications like valsartan?

19 A So at CP lab I started another
20 pharmaceutical company called NovaBay
21 Pharmaceuticals and that is immediately following CP
22 Lab and that company effectively was incubated
23 within CP Lab and within NovaBay I had multiple
24 interactions with the FDA. We manufactured product
25 according to CGMP and we put products on the market.

1 And prior to CP Lab, I worked at a pharmaceutical
2 company that was heavily involved in GMP
3 manufacturing and drug product, drug substance and
4 that one of the companies I worked for, Applied
5 Biosystems, in fact, you know, we had a challenging
6 impurity that was causing a lot of problem and I was
7 responsible for finding that impurity and solving a
8 major problem that led to an award, you know,
9 amongst 1,300 PhDs. This is back in 1994.

10 So -- but, you know, I don't have to have
11 experience in, you know, ARBs to know the molecule.
12 I can synthesize ARB personally.

13 Q Are you finished?

14 A Yes, I am.

15 Q All right. Then let me see if I can
16 get you to answer my question. At CP Labs did your
17 company have any role in the formulation, synthesis,
18 manufacture, production or testing of ARBs like
19 valsartan?

20 A No. At CP lab we did not have any ARB
21 manufacture.

22 Q You said that -- if I can unfold some
23 of that commentary that you gave me, was that CP
24 Labs was eventually folded into NovaBay
25 Pharmaceuticals, another company that you started?

1 A No. CP Lab is, you know, existing
2 company right now and it's a standalone company.
3 NovaBay was incubated within CP Lab and NovaBay got
4 its start from CP Lab.

5 Q So CP Lab still exists today?

6 A Yes it does.

7 Q Do you have any affiliation with CP
8 Lab?

9 A I own 50 percent of CP Lab.

10 Q Who owns the other half?

11 A My wife.

12 Q What's the business of CP Labs today,
13 do you know?

14 A CP Lab manufactures patented product
15 called ecological funnel, which is product that I
16 invented while I was at Applied Biosystem and that
17 patented product is the major product of CP Lab and
18 they manufacture it in the United States and they
19 export it around the world including China, Korea,
20 Japan and elsewhere.

21 They also distribute chemicals, distribute
22 safety product. So you can visit CPlab.com and take
23 a look at it.

24 Q What is an ecological funnel?

25 A It's a tunnel that prevents

1 evaporation of solvents from the fume. It's an
2 environmental product that prevents pollution
3 outside of laboratory. It prevents evaporation of
4 toxic substances, including mutagenic -- potentially
5 mutagenic compounds going into the atmosphere and
6 into the neighboring localities. And ecological
7 funnel is in use right now in, I would say,
8 90 percent of pharmaceutical companies worldwide.

9 Q When did you start NovaBay?

10 A NovaBay was incubated within CP Lab
11 around probably 1998; '97, '98 and officially it
12 became a company in the year 2000, and I took the
13 company public in 2007 and I left. I sold my shares
14 and left NovaBay in 2015 and started Emery Pharma.
15 And Emery Pharma, actually, again was incubated
16 within NovaBay starting at 2011.

17 Q Am I correct that NovaBay produces
18 antibacterial products for the eye care and skincare
19 markets?

20 A That's correct. That's some of their
21 products.

22 Q While you were at NovaBay, did the
23 company do any work on the formulation synthesis,
24 manufacture, production or testing of ARBs?

25 A We did not manufacture, synthesize,

1 formulate any ARBs at NovaBay.

2 Q Did -- while at NovaBay, did that
3 company ever prepare or submit an abbreviated new
4 drug application for any drug product?

5 A We did not prepare or submit any
6 abbreviated new drug application. However, we
7 submitted many INDs, investigation of new drug, and
8 we also submitted many 510-Ks from the drug or
9 device division of the FDA.

10 Q I guess was that because the focus at
11 NovaBay was to try to develop its own line of --

12 A Product.

13 Q -- probial products?

14 A Right. We were not a generic
15 manufacturing -- we were not a generic
16 pharmaceutical company.

17 Q So at no time at NovaBay were you
18 involved in synthesizing API for a generic
19 formulation, correct?

20 A We could have, but that was not the
21 mission of the company.

22 Q So it was never done?

23 A Never done.

24 Q And then at some point did you say
25 Emery Pharma was intubated?

1 A Incubated.

2 Q I'm sorry?

3 A Incubated.

4 Q Incubated. I said intubate. That
5 would not be correct.

6 A I heard "intubated."

7 Q Right. That's what I said. I did say
8 that. That was not correct, so I apologize.

9 And then eventually Emery Pharma became a
10 standalone company that you operate to this day,
11 correct?

12 A Correct.

13 Q And I think that if I understand what
14 you've previously described for us, the mission
15 statement and the function of Emery Pharma is to
16 provide research laboratory services that meet the
17 CGMP and GLP standards for quality?

18 A Emery Pharma is a FDA registered, FDA
19 inspected DMB, GLP compliant contract research
20 organization and our mission is to help save lives
21 and save the environment.

22 Q Does Emery Pharma develop or
23 manufacture drug products?

24 A Emery Pharma? That's not within the
25 mission of the Emery Pharma, no. We can, but we do

1 not.

2 Q Does Emery Pharma hold any new drug
3 applications?

4 A No, we do not. Our clients do.

5 Q Does Emery Pharma hold any abbreviated
6 new drug applications?

7 A We do not, but our clients do.

8 Q Has Emery Pharma ever prepared a DMF,
9 submitted a DMF?

10 A We do not, but we help our clients
11 essentially submit DMF and NDA and IMD and we
12 participate in their FDA meetings when necessary.

13 Q And I'm sorry. I think it was
14 probably due to sometimes there's sound that goes in
15 and out in the computer. You said you help clients
16 with submissions of what was that again?

17 A New drug application, abbreviated new
18 drug application; DMF filings; you know, support.
19 Just about anything that the client needs, we help.
20 We support them.

21 Q And how long has Emery Pharma been in
22 business?

23 A Since 2011, ten years.

24 Q Who are the clients for whom you've
25 help submit new drug applications or abbreviated new

1 drug applications?

2 A That's confidential information. I
3 wouldn't be able to share with you.

4 Q So you'll say that you have experience
5 helping to prepare ANDAs and NDAs, but you won't
6 tell us who you did it for?

7 A Yes.

8 Q Have you ever assisted a client in
9 preparing a DMF?

10 A Personally, no, but some of my
11 employees might have.

12 Q In your career, sir, have you ever
13 published any peer-reviewed literature related to
14 nitrosamine impurities in pharmaceuticals?

15 A Yes, we have. We filed a citizen
16 petition which was previewed by FDA and the response
17 we got from the FDA was they had agreed with our
18 findings, so I just would consider that very
19 peer-reviewed.

20 Q My question wasn't have you ever
21 submitted a citizens petition. My question was have
22 you submitted literature for publication in a
23 scientific journal that's been peer reviewed and
24 accepted that related to nitrosamine impurities in
25 pharmaceuticals?

1 MR. NIGH: Objection. You can answer.

2 A We have not filed any
3 nitrosamine-related publications in a peer reviewed
4 journals of our FDF filing.

5 Q The list of publications that were
6 attached to your CV that we marked as Exhibit 7, do
7 any of them feel with nitrosamine impurities in
8 pharmaceuticals in any manner or form?

9 A I do not believe they do.

10 Q Have you ever drafted a manuscript
11 related to nitrosamine impurities in valsartan for
12 publication in a peer review journal?

13 A We have drafted publication regarding
14 NDMA and nitrosamines, but not published.

15 Q Have you submitted a manuscript for
16 publication?

17 A No.

18 Q Why not?

19 A It's confidential. It's related to
20 another matter that we are working on related to
21 ranitidine.

22 Q Will you provide it to me?

23 A Daniel? I suppose I can.

24 MR. NIGH: We would have to see what
25 the document is. I think he just amended his answer

1 at the end to say it's for ranitidine and your
2 question is for valsartan.

3 MR. TRISCHLER: I think the question
4 was --

5 A It's under --

6 MR. TRISCHLER: Hold on. Hold on. I
7 think my memory is not infallible, Daniel, but what
8 I was basically asking is whether he's ever drafted
9 a manuscript that relates to nitrosamine impurities
10 in pharmaceuticals. I may have said valsartan, but
11 my intent was broader, and so it sounds like
12 something. The question is can I see it. It's not
13 been produced thus far.

14 MR. NIGH: We would examine the
15 document before we respond and answer to that.

16 MR. TRISCHLER: Well, it was subject
17 to the notice of deposition in this case. In the
18 deposition notice served in connection with this
19 deposition, I asked that the witness come here with
20 all publications relating to nitrosamines. That
21 would clearly -- this manuscript that he's described
22 would clearly be responsive.

23 MR. NIGH: I think you had our
24 response an hour ago.

25 MR. TRISCHLER: I'm sorry. Unless you

1 want to continue the deposition, I mean, this is my
2 chance to depose him on it.

3 MR. NIGH: I believe that 48 hours ago
4 we served our objections as clearly outside of the
5 scope of anything that is he's proffered in terms of
6 testimony in his expert here today.

7 MR. TRISCHLER: Well, as far as
8 outside the scope of his declaration, I disagree,
9 but I guess we will be taking it up again.

10 Q So you do have a manuscript --

11 MR. NIGH: And just to be clear --
12 sorry. Since you're saying something about taking
13 it up again, just so you understood too, I haven't
14 even looked at this document. So to the degree
15 you're asking about draft documents and
16 publications, obviously it would have potential
17 privilege as well.

18 A It's ranitidine related, but it's
19 nitrosamine.

20 Q Well, you've publicly disclosed the
21 existence of this manuscript, have you not?

22 A No.

23 Q Well, can you put up Exhibit 8 for us,
24 please. Do you recognize Exhibit 8?

25 A Yes, I do.

1 Q What is it?

2 A It's sort of a summary that one of my
3 team members wrote regarding our filing of our
4 citizen petition regarding ranitidine and how we
5 came about it, how we found the problem and how we
6 reported it to the FDA and how FDA actually agreed
7 with us and responded to our petition in a positive
8 manner. So that's really just the story of that.
9 There's nothing about this that contains anything
10 about that draft publication.

11 Q So this is what we have marked as
12 Exhibit 8, is basically a press release that was
13 issued by Emery Pharma, correct?

14 A Correct.

15 Q And I think this press release is
16 available on your website?

17 A Website. It's not a press release.
18 It's a blog.

19 Q All right, but this document and this
20 disclosure is on your website --

21 A That's correct.

22 Q -- for the public at large to view?

23 A Yes.

24 Q And in this document don't you state
25 or indicate that you're preparing a manuscript for

1 publication on the issue of nitrosamines in
2 pharmaceuticals?

3 A Right.

4 Q And if you could go to page 2 of this
5 document.

6 A Okay.

7 Q Can you highlight the second full
8 paragraph for me, please. Thank you. Are you able
9 to read that, sir?

10 A I'm reading it. Yes, I'm reading it.

11 Q So. Emery Pharma has publicly
12 disclosed that it's been testing valsartan, losartan
13 and other ARBs for nitrosamines since the early 2018
14 time period, correct?

15 A That's correct.

16 Q And there's nothing in these public
17 comments that you've made at the testing that we've
18 not been provided with it's something that's done
19 for litigation or confidential. You've told the
20 free world about it, right?

21 A We mentioned that we have been doing
22 that, but we haven't disclosed the results. The
23 results are confidential.

24 Q You are not a pathologist, true?

25 A Say that again, please?

1 Q You are not a pathologist?

2 A Pathologist?

3 Q That was my question.

4 A No, I'm not a pathologist.

5 Q Are you a medical doctor?

6 A I'm not a medical doctor.

7 Q Are you a toxicologist?

8 A I'm not a toxicologist.

9 Q Is it fair to say you're not a
10 epidemiologist and you do not have any specialized
11 training or expertise in the field of pharma
12 epidemiology?

13 A I am not a epidemiologist or any of
14 that.

15 Q Have you ever conducted and published
16 any peer-reviewed research on the carcinogenicity of
17 NDMA?

18 A No, I have not.

19 Q Have you ever conducted and published
20 any peer-reviewed research on the carcinogenicity of
21 NDEA?

22 A No, I have not.

23 Q Since you have no medical training, I
24 assume you do not diagnose cancer in patients; fair
25 to say?

1 A I am not a doctor.

2 Q And in this litigation I understand
3 you have not been designated as a witness on the
4 issue of causation, true?

5 A I am not a medical doctor.

6 Q Right. And you're not going to
7 testify -- well, we can agree you're going to be
8 offering causation opinions in this matter, correct?

9 A Explain to me what causation, what
10 your definition of causation here.

11 Q You're not going to be offering any
12 opinions that exposure to NDEA or NDMA did or can
13 cause cancer in humans?

14 A No, I am not offering any opinion on
15 the toxicology opinion on the NDEA or NDMA.

16 Q Have you ever published anything on
17 the requirements for a proper drug master file?

18 A No, I have not published any
19 requirement on anything on the requirements for drug
20 master file.

21 Q Have you ever published anything on
22 outlining the regulatory duties and responsibilities
23 of a generic drug manufacturer?

24 A We're not in the publication business.
25 We have not published anything. We are a contract

1 research laboratory testing facility with a lot of
2 experience in drug testing and impurity testing and
3 genotoxic testing.

4 Q Have you ever published anything or
5 given any lectures or speeches on the critical
6 review of the CMC sections and requirements for a
7 abbreviated new drug application?

8 A I have. I was invited to give a
9 presentation at a drug impurity symposium for
10 generic manufacturers and that presentation is
11 actually available. It's on the -- it should be
12 online YouTube or various other places.

13 Q Is it referenced on your CV?

14 A No.

15 Q When did you speak at this symposium?

16 A Probably early 2020, maybe mid 2020.
17 I can't recall.

18 Q We talked a little bit about Emery
19 Pharma's status as an FDA registered research lab.
20 What did you have to do in order to obtain that
21 registration, if anything?

22 A You basically submit an application to
23 the FDA and you register yourself with the FDA, and
24 as a result you become subject to FDA inspection.

25 Q When did you -- when did your lab

1 complete that application?

2 A I think maybe 2016, 2015, some time
3 frame.

4 Q When did you obtain the registration;
5 do you know?

6 A No, I don't, probably within a few
7 months.

8 Q How many FDA inspections have taken
9 place at your facility since?

10 A We've had two inspections from the
11 FDA.

12 Q When were those inspections?

13 A I can't recall; 2018 maybe one, 2021.

14 Q Were there any Form 483 issues
15 following those inspections?

16 A In our second inspection we had a Form
17 483 filled, yes.

18 Q That was the most recent one in 2021?

19 A That's right.

20 Q What was that for?

21 A It was primarily for, you know, making
22 sure our data gets backed up and we have -- we do
23 sufficient due diligence to make sure the data that
24 we generate gets backed up into a secondary backup
25 drive. So we have remedied that, and also to make

1 sure that our bend were open when we go to various
2 instruments, every user will have its own individual
3 log in, but we had no issues whatsoever on any of
4 our testing, any of our releases, any of our
5 products that are on the market.

6 There were just no issues on testing, but just
7 procedurally just data management, primarily backup,
8 and also specific user log-in, and both of those have
9 been remedied.

10 Q You said something that piqued my
11 curiosity, because I did not understand this to be
12 within the scope of anything you did. You said
13 something about our products. It was my
14 understanding that Emery Pharma does not manufacture
15 or sell any drug products. Am I wrong?

16 A No, you're not. We do not sell or
17 manufacture any drug product. However, we do
18 release them. So, another contract manufacturer
19 comes to us for a manufacture or a manufacturer
20 comes to us and says, please test my compound and
21 release them according to the guidance, ASP guidance
22 or GMP/GLP guidance.

23 So we officially release them and we identify
24 the drug, we identify their impurities and we release
25 them. So releasing is a terminology that's known to

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1 the FDA. It means it is ready to be sold into the
2 market.

3 Q Okay. And what you've suggested to me
4 is that in connection with the 2021 inspection, FDA
5 issued a 483 to Emery Pharma finding that certain
6 aspects of it or recordkeeping did not comply with
7 good laboratory practices, correct?

8 A What I said was that certain parts of
9 our data backup, data storage and backup did not
10 comply with the regs, and really it was a risk
11 management issue and their question was what happens
12 if there is an earthquake and then we lose all the
13 data.

14 So it needs to be backed up into the cloud so
15 in case of an earthquake, in case of fire we have
16 data that we can go back to.

17 Q Right. A form 483 is issued by an FDA
18 inspector after an inspection when that investigator
19 observes any condition that in his or her judgment
20 might constitute a violation of the Food, Drug, and
21 Cosmetic Act or its related regulations, right?

22 A That's correct.

23 Q And so what you're telling me is that
24 in 2021, your FDA-registered lab was found to have
25 conditions that in the opinion of the investigator,

1 constituted violations of the Food, Drug and
2 Cosmetic Act and its regulations as it related to
3 data management and data maintenance.

4 A What I said was the 483 -- first of
5 all, in our first inspection 2018 we had no problem,
6 no issues. In 2021 this issue came up that we need
7 to back up our data into the Cloud and it is really
8 part of the data management. And they basically
9 said we can continue our, you know, releasing
10 commercial products; we can continue our work. We
11 just need a commitment for you to get that done; and
12 since then we have gotten it done.

13 Q And so were any warning letters issued
14 following 483s?

15 A No.

16 Q Did -- what is Emery Pharma's status
17 with the FDA today?

18 A We are in the process of making those
19 data managements happen and they're completely
20 satisfied with that.

21 Q And so one of the things I take it you
22 learned from that most recent inspection, if not
23 earlier, was that data management, data preservation
24 and documentation are extremely important as it
25 relates to product testing, product release and

1 product validation measures.

2 A Data storage and back up are important
3 primarily -- you know, it's part of their risk
4 management strategy data integrity program making
5 sure the data is always there. You know, if God
6 forbid the facility catches fire or there is an
7 earthquake, we want to make sure the client's data
8 are there somewhere else. And that's something that
9 we had a backup system on the premises, but that was
10 not acceptable to them.

11 Q So, understanding the importance of
12 data preservation --

13 A Into the cloud. They wanted an offer
14 side data storage.

15 Q Let me ask my question, please.

16 A Sorry.

17 Q You're understanding the importance of
18 data preservation, I'm sure, then, you can tell us
19 with absolute certainty that all of the records --
20 that there will be records relating to all of the
21 valsartan testing that your lab has been doing since
22 early 2018, correct?

23 A That includes every data preservation
24 that that we have ever generated needs to including
25 valsartan that needs to have it back, have a back up

1 outside of our facility.

2 Q That would mean you'd have data on the
3 acquisition of samples, correct?

4 A Data on everything; acquisition. You
5 know even if somebody deletes the data or what have
6 you, everything needs to be backed up.

7 Q And so it needs to be backed up and
8 you've done that on the valsartan testing you have
9 data on acquisition of samples, correct?

10 A Acquisition of all samples including
11 valsartan. All samples need to have an off site
12 backup facility.

13 Q You'll have data of custody for all
14 valsartan samples?

15 A Yes, we do.

16 Q You'll have standard point operating
17 procedures and policies outlining the protocol that
18 weren't followed in connection with the test methods
19 that were used on the valsartan products, right?

20 A As an FDA registered, FDA inspected
21 GLP/gmp-compliant lab, everything we do is SOP
22 driven. So we have SOP's on everything.

23 Q Because you can't conduct a test and
24 then develop the protocol later, right?

25 A No.

1 MR. NIGH: Objection.

2 Q So you would be able to provide us
3 with a protocol pursuant to which all this testing
4 was done, correct?

5 A If it's not privileged, yes.

6 Q And do you have -- and you certainly
7 have all the test results for all of valsartan
8 samples that have been tested since the early 2018,
9 right?

10 A Absolutely. We have the test results
11 and we have reports, everything. If it is not
12 privileged, it would be available.

13 Q I'll represent to you that the
14 valsartan issue came to the attention of the FDA in
15 June of 2018.

16 A Right.

17 Q And your public statements that -- one
18 of which we marked as Exhibit 8 is you started
19 testing valsartan in early 2018. Are you suggesting
20 that you were doing valsartan testing for
21 nitrosamines prior to the time the FDA was even
22 aware that there was a potential issue?

23 MR. NIGH: Form objection.

24 THE WITNESS: Should I answer?

25 MR. NIGH: Yes.

1 A So initially the valsartan issue was
2 brought to our attention by a pharmacy out of
3 Connecticut called Valisure. I think we mentioned
4 their name in some of our blogs and big releases and
5 they brought it to our attention. They wanted to
6 test valsartan and they wanted us to test it for
7 them. They had some testing mechanisms and they
8 wanted us to confirm that. We did draw some samples
9 for them, some pills and we did confirm that.
10 That's our beginning of our engagement in the
11 valsartan arena and that was in 2018.

12 In 2019 we got engaged by law firm that is not
13 on this call, I believe, and they are -- so a lot of
14 the work we did relates to that but, yes, 2018 was
15 our initial work with valsartan.

16 Q And so -- thank you. That makes more
17 sense to me now. So the initial work that your lab
18 was doing with respect to analysis of valsartan was
19 done at the request of Valisure, not a lawyer?

20 A No.

21 Q Bad question on my part.

22 A That's correct. The initial work we
23 did on valsartan was done at the request of
24 Valisure.

25 Q And you would have, consistent with

1 your labs, stated desire to follow good laboratory
2 practices, you would have all of the chain of
3 custody sample, acquisition data, protocol data,
4 test validation data and testing summaries from that
5 Valisure work?

6 A Yes, I do.

7 Q None of which has been provided to me,
8 right?

9 A I don't believe so.

10 Q Do you know what the results of that
11 work was, what nitrosamine did you test and what
12 were the results?

13 A You know, I wasn't sure if any of
14 these things are subject of our -- you know, my
15 declaration, but the results were very high levels
16 of nitrosamines, high levels of NDMA in the
17 thousands of nanograms.

18 Q Do you know whose valsartan you were
19 testing?

20 A No.

21 Q In 2018 at the request of Valisure?

22 A No, I don't. We have records of that.
23 We should be able. Right off the bat, I don't. It
24 might have been Mylan, Teva, Aurobindo, a number of
25 manufacturers we might have been testing.

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1 Q If we go back to your declaration for
2 a minute -- bear with me a minute. My exhibits
3 disappeared from my screen, so we have to find it
4 again. If we go to your declaration, we marked it
5 as Exhibit No. 1?

6 A Would you mind? I'd like to take a
7 quick break, five minute break.

8 MR. NIGH: Yeah, let's take a ten
9 minute break.

10 THE WITNESS: Ten minute break? Okay.

11 THE VIDEOGRAPHER: The time is 12:47.
12 This ends Media 3.

13 (A recess was taken.)

14 (After the recess the following
15 occurred:)

16 THE VIDEOGRAPHER: The time is now
17 1:00. This begins Media 4. You may proceed.

18 BY MR. TRISCHLER:

19 Q I wanted to ask you a couple followup
20 questions on some of the issues that we covered
21 before the last break, Doctor. We talked about the
22 2021 FDA inspection of Emery Pharma. Do you recall
23 that?

24 A Yes.

25 Q And what I wasn't clear about is what

1 is the current status of that 483, is it open or
2 closed?

3 A It's in the process of closing,
4 because what happens is you're working toward
5 getting, basically, backup system, Cloud system
6 essentially working, you know, and validated an all
7 of that. So that's been in the process of
8 implementation and validation as we speak.

9 Q So "in the process" means that it's
10 still open?

11 A It's still open.

12 Q And is your lab on OAI status?

13 A What's OAI?

14 Q Official action indicated, I think is
15 what it stands for.

16 A I have to check with my QA people.

17 Q Was an establishment inspection report
18 issued; do you know?

19 A I don't know.

20 Q What -- and then going back to your
21 early valsartan work in the early part of 2018, you
22 said that that was prompted by a contact from
23 Valisure that asked you to do some testing. Can you
24 tell me who or what information you received from
25 Valisure that caused them to be interested in

1 testing valsartan before the FDA was even aware of
2 an issue?

3 A So, you know, to be very frank to you,
4 I don't know whether it was done before FDA official
5 recall or after. I would have to check on that, but
6 I was contacted by the president of Valisure David
7 Light and he wanted us to check the levels of NDMA
8 in valsartan.

9 Q And you agreed to do that at his
10 request?

11 A And he had data already. He also had
12 GCMS data that showed high levels of NDMA genotoxic
13 compound, and so I was very concerned because
14 actually my mom was taking valsartan a few years
15 ago, so I agreed to do the work. We might not have
16 even charged them.

17 I think we probably charged them, I don't
18 know, but we ran the same pills that they had ran and
19 we corroborated their data that indeed there were
20 high levels of NDMA in valsartan, and we might have
21 tested for NDEA as well. I'm not sure.

22 Q What test method did you utilize
23 during that initial testing?

24 A We used two or three official FDA
25 methods that has been published. I think we used

1 one of those methods.

2 Q Well, the FDA didn't publish -- this
3 is the thing that's confusing to me trying to piece
4 together the timeline. FDA didn't publish a test
5 method for nitrosamine testing until the fall of
6 2018.

7 A Right.

8 MR. NIGH: Form objection.

9 Q So that's why I asked what test method
10 were you and Valisure running.

11 A I would have to get that. I don't
12 know. For the purpose of this deposition I really
13 was not prepared to discuss any of that, but I am
14 not prepared. It's not in my declaration.

15 Q So let's go to the declaration, if I
16 can. It's paragraph -- first part I want to talk to
17 you about is paragraph 2 of the declaration I think
18 you said you have in front of you, Doctor.

19 A If you want me to elaborate on that, a
20 lot of that was published in citizen petition by
21 Valisure and I think some of our data I think he
22 mentioned the data levels and all of that and the
23 methods may be actually there as well.

24 Q Were you talking about the Valisure
25 petition relating to ranitidine?

1 A Valsartan. I think they did have
2 something on valsartan as well.

3 Q Did you ever file a citizens petition
4 related to valsartan?

5 A No.

6 Q And when I say "you," I also mean
7 Emery Pharma?

8 A No.

9 Q You think Valisure did?

10 A Maybe I'm mistaken. I think they
11 have. You can Google it. I may be mixing it with
12 their citizen petition relating to ranitidine.

13 Q I'm glad you brought it up, because it
14 sort of led to another question that I had that
15 wasn't clear to me.

16 You were quick to tell me that part of the
17 mission statement of Emery Pharma is to save lives
18 and preserve the environment. Do you remember
19 telling me that?

20 A FDA -- I mean Emery Pharma's mission
21 is to helping our client save lives and save the
22 environment.

23 Q And that was part of the rationale
24 behind your issuance or decision to prepare and
25 submit a citizens petition relating to ranitidine?

1 A We filed -- a lot of the work we did
2 on ranitidine was done at our own expense, at our
3 own behest primarily for the safety of the public.
4 And we do that all the time; public comes to us and
5 they want us to look at something. If they don't
6 have the proper funding, we do it at pro bono and we
7 check the drug for various impurities and problems.

8 Q But the work you're doing in
9 ranitidine and valsartan is not pro bono, is it?

10 A So some of the work may be pro bono.
11 A lot of the work that we did on ranitidine citizen
12 petition, almost 100 percent of the work that was
13 done for citizen petition was pro bono.

14 Q Okay. Why did you never submit a
15 citizens petition with respect to valsartan?

16 A I think there wasn't any necessity for
17 that. I think there was -- you know, obviously
18 valsartan, it was recalled and I think Valisure was
19 making a lot of noise, so it was already the public
20 was alerted. And my goal as the CEO of Emery Pharma
21 is if there is a problem with a drug, I will alert
22 the FDA through some form of petition, and we
23 recently actually filed a citizen petition on
24 vitamin B6. You may be taking vitamin B6. You may
25 want to read it; and, again, entirely at our own

1 expense.

2 Q Is that your second citizens petition
3 then that you were submitting?

4 A Yes.

5 Q Have there been any others since then?

6 A No.

7 Q And you said Valisure was making a lot
8 of noise about valsartan, but have you ever seen a
9 citizens petition from them?

10 A I don't recall.

11 Q With regard to valsartan?

12 A My memory is failing. I think -- I
13 don't think valsartan -- I mean, you guys can google
14 it, whether Valisure filed any citizen petition on
15 valsartan. I don't think so. I think they just
16 made a lot of press release, but I think the
17 valsartan was removed from the market primarily due
18 to Novartis finding genotoxic compound NDMA in
19 valsartan from GMP and then effectively FDA was
20 alerted. I think that's how the things kind of --
21 how sort of everything fell into the, you know,
22 basically the recall.

23 Q Did you have any -- have you ever had
24 any communications with Novartis about valsartan
25 testing?

1 A None.

2 Q Have you ever had any communications
3 with Novartis about Diovan testing?

4 A None.

5 Q Have you ever had any communications
6 with Novartis about Exforge testing?

7 A None.

8 Q So going to paragraph 2 of your
9 disclosure or declaration -- excuse me, I want to
10 ask you about the last sentence in particular where
11 you talk about the methodologies that you employed
12 in formulating your opinions in this case and you
13 write, "These methodologies used in formation of my
14 opinions are also used by Emery Pharma in making
15 recommendations to our pharmaceutical clients." Did
16 I read that correctly?

17 A Yes. Just let me read it. Yes, I
18 agreed with that.

19 Q And based on what you already told me,
20 I take it you're not going to tell me who your
21 pharmaceutical clients are you are referring to in
22 paragraph 2?

23 A I cannot. We are under
24 confidentiality.

25 Q So you can suggest that you're

1 following a methodology that you employ about your
2 clients but then conveniently not tell me who the
3 clients are, right?

4 A We are under obligation from the
5 clients not to disclose their name.

6 MR. NIGH: Form objection.

7 Q Are any of these clients defendants to
8 the ranitidine litigation?

9 A No.

10 Q Are any of them defendants to the
11 metformin litigation?

12 A No.

13 Q Are any of them defendants to this
14 litigation, if you know?

15 A No.

16 Q Are any of the unknown undescribed
17 clients that you make reference to, are any of them
18 generic drug manufacturers?

19 A No.

20 Q Did any of them manufacture ARBs?

21 A No.

22 Q So you don't have any clients that you
23 would be advising on the contents of an abbreviated
24 new drug application, correct?

25 A We do have clients that we advised on

1 the contents of new drug application and abbreviated
2 new drug application. However, none of them are the
3 defendants. None of them are the plaintiffs. None
4 of them are manufacturing ARBs as far as I know and,
5 you know, these are -- we work on mostly branded
6 products, some generic, sort of modified generic,
7 branded generic but nothing to do with ARBs.

8 Q Well, what generic -- excuse me. What
9 generic products are you working on with generic
10 drug manufacturers?

11 A I can't think of it right now. I mean
12 a number of them -- there are a number of products
13 that we are working on.

14 Q Well, if these products have a patent
15 there is no secrecy to the identity of the active
16 pharmaceutical ingredient that you're working on
17 with the --

18 A I can't recall off the top of my head
19 what generics we're working on.

20 Q So as you sit here today you can't
21 tell me a single generic product you're advising a
22 client about?

23 A No.

24 Q Have you ever told any of your
25 pharmaceutical clients who manufactured generic

1 drugs that their products are adulterated if their
2 impurity profiles do not match the RLD?

3 A I have told our clients that if their
4 impurity profile contains a genotoxic compound, we
5 will let them know.

6 Q Thanks. That wasn't my question. My
7 question is have you ever told your clients that
8 they will be producing an adulterated generic
9 product if they have an impurity profile that does
10 not match the RLD; is that advice that you've ever
11 given to your pharmaceutical clients in the real
12 world?

13 A Okay. So, here is my answer. If
14 their impurity profile -- you know, their impurity
15 profile may not match the RLD. However, if their
16 impurity profile contains genotoxic compound, we
17 will let them know and we will help them to prevent
18 formation of genotoxic compound.

19 Q Okay. That's fair. So the mere
20 differences in the impurity profile alone does not
21 make a drug adulterated?

22 A Right.

23 MR. NIGH: Form objection.

24 A Mere --

25 THE WITNESS: Can I respond, Daniel?

1 MR. NIGH: Yes.

2 A A mere difference -- we have repeated
3 this question many times. I will repeat it.
4 Hopefully you guys can go back and see I am very
5 consistent. Mere difference in the impurity profile
6 so long as there is no genotoxic compound, it's
7 fine.

8 Q And the fact of the matter is the FDA
9 permits variability in purity, size, strength and
10 other parameters when evaluating an abbreviated new
11 drug application, agreed?

12 A FDA allows variability in the impurity
13 profile with respect to the reference listed drug as
14 long as it does not contain genotoxic compound --

15 Q And we talked about --

16 A -- namely nitrosamines.

17 Q We talked about the acceptance
18 criteria for impurities as published in the USP
19 being no more than 0.1 percent. Do you remember
20 that?

21 A I remember the acceptance criteria of
22 the USP not showing any NDMA and not having any
23 limits on the NDMA. To me that means zero NDMA.

24 Q So the fact that what the USP monitor
25 says is that unknown impurities can be no more than

1 0.1 percent, right?

2 A Unknown non genotoxic impurities can
3 be around .1 percent or a little higher.

4 Q But what you're saying is the
5 monograph itself is silent as to genotoxic
6 impurities, correct?

7 A Their silence is because they assume
8 zero NDMA. They assume zero genotoxic brought.

9 Q And that's written nowhere in the
10 monograph itself or in any USP publication, correct?

11 A Exactly. Because it's not written, it
12 means it should be nonexistent.

13 Q And --

14 A Because the RLD was nonexistent,
15 because the Diovan and Exforge had no NDMA.

16 Q Are you aware of any drug manufacturer
17 anywhere in the world that was doing
18 nitrosamine-specific impurity testing prior to FDA's
19 notification of the potential for nitrosamine?

20 A Yes, I am. I am aware.

21 Q In 2018?

22 A Yes, I am aware of a pharmaceutical
23 company that does test for NDMA.

24 Q And who is that?

25 A Novartis, at least one which is

1 Novartis.

2 Q How do you know -- excuse me. How do
3 you know what test methods Novartis was using prior
4 to June of 2018, what's your source of information?

5 MR. NIGH: Outside the scope.

6 A Prior to 2015 -- sorry, 2018, all I am
7 aware is that Novartis discovered the NDMA in the
8 ZHP product and it's because they were looking for
9 it. They found it. They were testing it. They had
10 space and they saw the impurity and identified the
11 impurity. It takes no more than 10 minutes by
12 running a GCMS to identify NDMA.

13 Q My question is what is your source of
14 information that Novartis was doing nitrosamine
15 testing prior to June --

16 A Public information.

17 MR. NIGH: Outside the scope.

18 Q Can you cite me to that public
19 information, because I've never seen it.

20 MR. NIGH: Outside the scope.

21 A European medical authority has written
22 about it. It was to, you know, basically -- I think
23 that's part of EMEA in one of their reports I recall
24 seeing it that they mentioned that Novartis saw it
25 or maybe it was chemical engineering news, but I

1 think you can Google it. You should be able to see
2 Novartis. Just type in Novartis nitrosamine
3 impurity. I think you will run into chemical
4 engineering news. I might have been cited there was
5 well.

6 Q Didn't you develop specialized test
7 methods to test for nitrosamines in the latter parts
8 of 2018 and 2019?

9 A I don't believe so.

10 MR. NIGH: Objection. Outside the
11 scope.

12 A I don't believe so. I think we used a
13 standard nitrosamine methodology.

14 Q Did you develop a liquid LCMS method?

15 A We did. We developed our own LCMS
16 method primarily not for valsartan, but for other
17 drugs.

18 Q For Zantac?

19 A Yes.

20 Q So if we look at --

21 A And beyond Zantac. We also tested
22 probably 20 other drugs as well.

23 Q Twenty other drugs for nitrosamines?

24 A Yes.

25 Q How did you pick what 20 drugs you

1 were going to test?

2 A We look at structural clues. You look
3 at structural clues in a pharmaceutical molecule and
4 you say this molecule could be prone to NDMA
5 formation and that's called structural clues. If
6 someone skilled in the art of chemistry looks at
7 valsartan synthesis, there are -- it's shouting.
8 That synthetic route is shouting that it's going to
9 be forming a NDMA. We use those kinds of structural
10 clues to look at other compounds to see whether they
11 form NDMA or not.

12 Q What are the 20 other drugs you
13 tested?

14 A I can't -- off the top of my head I
15 can't recall.

16 Q Can you recall any of them?

17 A We looked at -- obviously we looked at
18 nizatidine, which is a cousin of ranitidine. We
19 looked at famotidine, which is also an anti-acid.
20 We looked at a whole bunch of antacids, you know,
21 and we might have looked at some over-the-counter
22 sort of diphenyl hydramine; you know, things like
23 that.

24 MR. TRISCHLER: I'm sorry. I need to
25 take a break. I've got something I need to take

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1 care of. I had an appointment scheduled for 4:30
2 that I realize I'm going to have to cancel, so I
3 need a couple minutes to take care of that. Sorry,
4 Dan.

5 MR. NIGH: What's the problem? Let's
6 take a ten minute break.

7 THE VIDEOGRAPHER: The the time is
8 4:24. We are going off the record.

9 (A recess was taken.)

10 (After the recess the following
11 occurred:)

12 THE VIDEOGRAPHER: The time is now
13 1:36. We're back on the video record.

14 BY MR. TRISCHLER:

15 Q So, Doctor, you have told me that it
16 is -- that it's your opinion that a drug company
17 should not sell a product with any nitrosamines,
18 correct?

19 A That's what I said.

20 Q And we talked about the fact that the
21 regulations allow unknown impurities as high as
22 300,000 nanograms for a 320-milligram tablet
23 product, you interpret that requirement that USP
24 specification as saying it applies only to non geo
25 toxic?

1 A Genotoxic.

2 MR. NIGH: Form objection.

3 Q Right. It applies only to non
4 genotoxic?

5 MR. NIGH: Form objection.

6 A I don't understand your question. My
7 apologies. Could you repeat?

8 Q Yes, I will ask again.

9 A Could you ask a specific question?

10 Q I will ask it again. I was trying to
11 make sure I understood your testimony. I think I
12 do, but what you've told us is the USP specification
13 that allows for unidentified impurities to be as
14 high as 300,000 nanograms in a 320 milligram product
15 only applies to non genotoxic impurities?

16 MR. NIGH: Form objection.

17 A That applies to non genotoxic
18 impurities.

19 Q Right. If I misspoke, I apologize.

20 A Right.

21 Q That's what I understood, and that's
22 because you interpret the absence of any
23 specification in USP as a dictate or a mandate that
24 the requirement for genotoxic impurities must be
25 zero?

1 MR. NIGH: Form objection.

2 A Let me explain. So requirement for
3 genotoxic impurities are far lower than regular
4 impurities. So you must have a lot less genotoxic
5 impurities in your drug and the levels are listed.
6 In the case of specifically nitrosamines and
7 specifically NDMA, the requirements should be zero.

8 Q And you indicated that you were aware
9 of at least one company prior to 2018 that was
10 testing its product and making sure that its
11 valsartan nitrosamine levels were zero, and that
12 company was Novartis?

13 MR. NIGH: Form objection.

14 A As far as I know, there may be many,
15 many more companies testing their compounds for
16 nitrosamines, but as far as I can tell from,
17 basically, public records, you know, NDMA --
18 obviously Novartis looked for NDMA. Novartis found
19 NDMA in their API, and I can only give you my
20 opinion that Novartis perhaps -- they buy a lot of
21 APIs from China and India. Perhaps they look for
22 NDMA in every API they buy.

23 Q And do you -- you indicated that or
24 you offered the opinion that a drug company that
25 sells a pharmaceutical product that contains a

1 genotoxic impurity at any level or any concentration
2 is not equivalent to the reference listed drug
3 because the reference listed drug does not have
4 genotoxic impurities, right?

5 MR. NIGH: Form objection. You could
6 answer.

7 A The genotoxic drugs, you know, have
8 limits that they need to abide by in an active
9 pharmaceutical ingredients and there are specific
10 numbers and the numbers, Clem, is not 300,000 parts
11 per million. It's in the hundreds of parts per
12 million, maybe even much less.

13 In the case of nitroso, nitrosamines and the
14 n-dimethyl nitrosamine the requirements are zero
15 because this is a genotoxic, DNA reactive,
16 cancer-causing molecule. And furthermore, FDA says
17 the levels should be zero because there are synthetic
18 methodologies. In layman's terms there are recipes
19 to make valsartan without any NDMA, so manufacturers
20 should use that recipe. And, you know, that's my
21 opinion and I think the levels should be zero for
22 NDMA.

23 For other genotoxic compounds there are
24 specific levels and one has to consult with ICH
25 guidelines, ICH M7 for those levels.

1 Q Okay. Well, that's fair. I'll try to
2 confine my questions to NDMA and NDEA. Okay?

3 A Thank you.

4 Q And if I understand your opinion, what
5 you've told us is that you're of the opinion that a
6 generic formulation that contains NDMA or NDEA is
7 not equivalent to Diovan or Exforge, because those
8 reference listed drugs have zero NDMA and zero NDEA?

9 A The generic drugs that contain NDMA do
10 not meet the requirement. I have not tested Diovan
11 or I have not tested Exforge. I can only assume
12 that they are -- they have zero NDMA because they
13 were not recalled, so that's what I said.

14 Q Well, yeah, and that's what I wanted
15 to get at in terms of trying to understand what we
16 have here today.

17 The opinion that we framed earlier was -- that
18 you intend to offer is that the generic drugs made by
19 valsartan-containing medications made by my client
20 and some of the other defendants for this litigation,
21 you do not believe those drugs are equivalent to the
22 reference listed drug, because you have assumed that
23 the defendant's generic products contained NDMA and
24 NDEA and you assumed that the Diovan and Exforge did
25 not?

1 MR. NIGH: Form objection.

2 Q Right?

3 A If the manufacturer does not comply
4 with the impurity limits which is really zero, they
5 are responsible -- and they change their procedure,
6 they change their recipe, they change the way they
7 make something, then they need to -- there are these
8 alerting structures. I'm kind of giving away a lot
9 of my opinion that will come later, which is there
10 are alerting structures. These are clues for you.
11 Those alerting structures were ignored and, hence,
12 they now have to deal with NDMA and all the issues
13 and --

14 Q I appreciate the sneak preview, but I
15 honestly don't want to go there. What I just want
16 to understand is --

17 A The assumption.

18 Q Perhaps if you will let me explain, I
19 can ask a question that's fair and easy to
20 understand, Doctor. I just want to make sure I
21 understand the assumption that forms the basis for
22 your opinion that you've offered so far in the
23 declaration we have.

24 You told me that there's two core opinions.
25 One of them is that generic drugs at issue in this

1 litigation are not equivalent to the reference listed
2 drug and you have reached that opinion based on the
3 assumption that the reference listed drugs contain
4 zero NDMA and zero NDEA, right?

5 A Mm-hmm.

6 Q Is that "yes"?

7 A Yes.

8 Q Okay. And one of the things that
9 jump-started you in this arena and I presume
10 provides you some basis for that assumption is you
11 started working with Valisure on nitrosamine testing
12 of valsartan before there was even litigation,
13 right?

14 A So, Clem, as I have stated before, I'm
15 not sure when we have actually officially started
16 with Valisure. It might have been before, it might
17 have been after, but that's what I can tell you.

18 Q Fair enough.

19 A I'm sure if Daniel would be okay, I
20 can, you know, get that information to you.

21 Q Fair enough.

22 A But the fact remains that whether if
23 before or after we tested your client's pills, maybe
24 your client's pills, honestly I don't know, I'm not
25 prepared to tell you what we have until I can give

1 you reports of those, but they had high, high levels
2 of these genotoxic compounds. And I wouldn't want
3 anybody to be taking those drugs, you know, on long
4 term basis because that would be -- you know, that
5 wouldn't be good whether it would be my mother or
6 your mother.

7 Q Well, my mother already passed, so I'd
8 be happy to have her take valsartan with or without
9 genotoxic impurities right now.

10 A I'm sorry to hear that.

11 Q But be that as it may, what I was --
12 and I didn't mean to misstate your testimony about
13 the timing of your work with Valisure. You did tell
14 me you couldn't be sure whether it was before or
15 after the FDA involvement, so I grant you that.

16 A Yes.

17 Q But what you did talk about and what
18 you did explain to me was that Valisure brought the
19 issue of the potential for nitrosamines in valsartan
20 to your attention and sort of asked you to help with
21 the testing and evaluation, right?

22 A One hundred percent.

23 Q Okay. And so you had a chance to look
24 at the testing that was done by Valisure early on on
25 the valsartan and to independently validate it

1 through the work of your own lab?

2 A Yes, we did.

3 Q So there is no question in your mind
4 that the results of testing as documented by
5 Valisure and its findings on nitrosamine contents in
6 valsartan were accurate?

7 A We repeated Valisure's work according
8 to our own procedures and we, I think we -- the
9 result what we told Valisure was that the numbers
10 they got was pretty much in the ballpark.

11 MR. TRISCHLER: Did anyone hear the
12 doctors' answer? I saw his lips moving but didn't
13 hear anything.

14 MR. NIGH: I could hear it.

15 A I said. Let me repeat. Can you hear
16 me okay?

17 Q Now I can.

18 A Okay. What I said was we concurred
19 with Valisure that they had correct nitrosamine
20 numbers for their valsartan pills and they sent to
21 us the same pills that they tested. I specifically
22 warned Valisure to get it tested at a third-party
23 lab. He called me, asked me for my advice. I said
24 you want to get it at a third party lab to make
25 sure. I think he was planning to do some press

1 release or something, and that's what we did. And
2 we told them yes, I think, and then he basically did
3 something with that data. So...

4 Q Okay. And then you mentioned -- and
5 so essentially I think you just answered what my
6 question was. My question was, did you have the
7 opportunity and did in fact independently
8 corroborate the Valisure data as it related to
9 valsartan nitrosamine quantification?

10 A That's correct. We corroborated their
11 data.

12 Q And then you made mention early on --
13 I shouldn't say early on. You paid mention before
14 our last break about a citizens petition and you
15 suggested that you thought somewhere in your memory
16 bank that Valisure might have done a citizens
17 petition that might have related some way or somehow
18 to valsartan. Do you remember that?

19 A Yes. I don't think they have.

20 Q I found something I want to ask you
21 about, and Frank from my office is there.

22 MR. TRISCHLER: Frank, do you have the
23 June 13, 2019, Valisure citizens petition and can
24 you have that marked as the next numbered exhibit?

25 MR. STOY: Yes. I just uploaded it a

1 minute ago. Bill, do you have it?

2 THE VIDEOGRAPHER: I have it. I am
3 downloading it. Just give me one moment. For the
4 record, that would be Exhibit 28 is the next one in
5 line.

6 MR. TRISCHLER: Okay. Can you put up
7 Exhibit 28, please.

8 Q This is on the Valisure letterhead
9 dated June 13, 2009.

10 A Right.

11 Q Take a look at the first couple
12 paragraphs. Does it refresh your recollection at
13 all?

14 A Now I recall. I think they did file
15 something with the FDA, but this is regarding DMF, I
16 think.

17 Q You're correct that it does relate to
18 dimethylforamide which is DMF, right?

19 A Dimethylformamide.

20 Q Formamide, okay? I'll try to do
21 better. I didn't do very well in chemistry.

22 A No, no. I just get insulted when they
23 mispronounce these chemical names, that's all. No
24 worries.

25 Q I was trying to say the chemical name

1 to distinguish from DMF to refer to drug --

2 A Yeah.

3 Q So dimethylformamide is subject of
4 Exhibit 28, correct?

5 A Correct.

6 Q But there's also reference to NDEA
7 testing was done by Valisure IN this citizens
8 petition, correct?

9 A Right.

10 Q As I said, you saw this citizens
11 position before.

12 A Right.

13 Q And you had validated the test results
14 that are reported in here?

15 A Yes.

16 Q And if we look at Appendix A to the
17 report, what we have is a summary of NDMA levels and
18 DMF levels in valsartan tested by Valisure and
19 confirmed by your lab?

20 A Did they mention our name in this
21 report, can you Google it?

22 Q I don't know, but --

23 A If they didn't mention our name, then
24 we didn't have anything to do with it.

25 Q Well, you already told me that you had

1 validated their testing and corroborated the
2 results, right?

3 A NDMA?

4 Q Right.

5 A NDMA, but that's if they mentioned our
6 name, then it would be corroborated, but if they
7 didn't mention our name, it was on their own.

8 Q Well, I only planned on asking you
9 about the NDMA results reported in this.

10 A Please.

11 Q As you said at least five or six times
12 it's called by Valisure to corroborate their data?

13 A Yes, but you know -- okay. Go ahead.

14 MR. NIGH: Form objection.

15 Q So if you look at the Appendix A,
16 you're looking at the first page there. If you flip
17 to the next page, page 10, there's more results
18 reported. Do you see that?

19 A Right.

20 Q Page 111 there's more results
21 reported?

22 A I don't think we tested that many
23 different pills and lots for them.

24 Q I am only asking about what's shown
25 here in the document. There's more testing

1 reported, correct?

2 A Okay.

3 Q And the manufacturers whose product
4 was tested was also identified in Appendix A,
5 correct?

6 A Mm-hmm.

7 Q Is that "yes"?

8 A Yes.

9 Q Interestingly, one of the
10 manufacturers is Novartis.

11 A Okay.

12 Q And if you look at page 12, there is
13 results of seven test samples of Novartis product
14 listed, correct?

15 A Right.

16 Q There was NDMA found in every single
17 Novartis tablet, correct?

18 A Yes.

19 Q Is that correct?

20 A That's what you're showing me.

21 Q So your assumption that underlies your
22 opinion in this case that Novartis' valsartan
23 contained zero NDMA is not supported in the testing
24 done by Valisure and it was validated by your lab.

25 MR. NIGH: Form objection.

1 MR. TRISCHLER: What's that?

2 MR. NIGH: I just said "form
3 objection."

4 MR. TRISCHLER: I meant what's that to
5 the witness.

6 A And I respond to that I'm not -- I
7 cannot confirm to you that we corroborated it
8 everything that Valisure is presenting in this
9 report vis-a-vis the fact that our name has not been
10 mentioned on this citizen petition.

11 Typically if we do not corroborate something,
12 they shouldn't put our name. If they are not putting
13 our name, it means we didn't have anything to do with
14 these.

15 Q Your assumption that Novartis, Exforge
16 and Diovan formulations contained zero NDMA is not
17 supported in the data from the citizens petition of
18 Valisure, is it?

19 A Based on what Valisure is reporting
20 to, you know, I cannot corroborate their data
21 because we didn't do it. This is their data.

22 Q And their data does not support your
23 assumption. That's all I asked.

24 A If their data is correct -- you know,
25 I don't know if they are data is correct. Now

1 having said that, you know, Clem, the levels that
2 were -- the interim allowable limit of NDMA, as you
3 know, is 96 nanograms. So under the recall,
4 official recall and notice, anything under 96
5 nanograms would not be recalled. So Novartis would
6 not be a recalled product.

7 Q I didn't ask you if it would be a
8 recalled product and you were also very clear to me,
9 Doctor, that NDMA and NDEA content in its drug
10 product must be zero. You said that five times to
11 me.

12 A That should be the goal of the
13 manufacturers to have zero NDMA and NDEA.

14 Q And you criticized my clients because
15 they had NDMA and NDEA levels higher than zero.

16 A They had levels of 2,000 and 3,000
17 nanograms.

18 MR. NIGH: Hold on. Hold on. Hold
19 on. Hold on. Form objection. Does he even know
20 your client?

21 MR. TRISCHLER: He's your expert. I
22 don't know.

23 MR. NIGH: Okay, because we are
24 getting way off comment on some of these topics. He
25 has not said in terms of your client.

1 MR. TRISCHLER: He just said my
2 client.

3 Q Dose levels of 2,000 nanograms; is
4 that your testimony, sir?

5 A I don't -- I am going on what was
6 published by FDA. So you can Google that and see
7 what FDA was published and double check that to see
8 if your clients is part of that FDA recall and FDA
9 numbers.

10 Q I can do a lot of things, Doctor. I
11 spend way too much time online. What I'd like to do
12 is ask you questions. And my question is, is it
13 your testimony that Mylan had NDEA reported at
14 levels of 2,000 to 3,000 nanograms in its
15 valsartan-containing products?

16 MR. NIGH: This is far outside the
17 scope of his certification and declaration at this
18 point. I mean, you can read it. He doesn't mention
19 a single thing about Mylan.

20 MR. TRISCHLER: He volunteered and I
21 am allowed to follow that up.

22 MR. NIGH: No, that's not actually
23 true. I have a lot of questions to go far outside
24 the scope at this point, but this is way outside of
25 the scope of his seven page declaration. Not a

1 single place in here does he ever mention any of the
2 defendants' testing levels and I think you know
3 that. So, again, at this point we're getting way
4 outside. I have allowed some exploration at some
5 point, but this has no basis in his declaration at
6 this point.

7 MR. TRISCHLER: I think I'm entitled
8 to an answer to the question. You've objected. You
9 can argue whether --

10 MR. NIGH: I am going to instruct him
11 not to answer at this point. We have gone far
12 outside the scope.

13 MR. TRISCHLER: Just so that I'm
14 clear, the witness stated that my client had levels
15 of 2,000 to 3,000 nanograms and you are not allowing
16 me to follow up on that?

17 MR. NIGH: Just so you're clear, I
18 think that question was far outside the scope in the
19 first place. He is not here to offer an opinion as
20 to what the levels are or your client's levels. He
21 is not here to offer an opinion as to what any of
22 the clients' levels are. His opinion clearly states
23 valsartan which contaminated NDMA or NDEA, period,
24 not about levels.

25 Q You told us, Doctor, generic drug

1 products contain any NDMA, NDEA is not equivalent to
2 Novartis who is the reference listed drug holder,
3 because Novartis' levels are zero. The data from
4 Valisure suggests that that's not true. Agreed?

5 A My position is that levels of NDMA and
6 NDEA should be zero in any valsartan pills.
7 Novartis might have some valsartan at higher level,
8 have some NDMA in it. They might have had -- in
9 fact, they were buying -- from my understanding they
10 were buying ZHP's API and they were using ZHP's API,
11 so I am not surprised they ended up with some NDMA,
12 but prior to ZHP and any of the defendants' products
13 Diovan and, you know, Exforge going generic, I
14 believe they had their procedure, their process
15 produced no NDMA.

16 Q Have you ever reviewed the new drug
17 application for Diovan?

18 A I have reviewed a lot of documents,
19 yes.

20 Q I didn't ask if you reviewed a lot of
21 documents. Have you ever reviewed the new drug
22 application for Diovan?

23 A I have reviewed it.

24 Q Where did you get it?

25 A You know, I think maybe, you know, the

1 plaintiff's lawyer shared it with me.

2 Q I'm surprised that Novartis would turn
3 over their proprietary documents to the plaintiff's
4 lawyers. So your testimony is you've seen the new
5 drug application?

6 A I might have seen it. I reviewed a
7 lot of different documents.

8 Q Well, it was not disclosed or provided
9 in any of the materials that were given here to me.

10 A I cannot recall, but I reviewed a lot
11 of different documents relating to valsartan
12 manufacturing; valsartan -- you know, there is a lot
13 of public information regarding the manufacturing
14 process.

15 Q Chemistry manufacturing controls
16 submissions as part of Novartis' new drug
17 application. It's not public information, is it?

18 A What is your question?

19 Q I just asked you that one. There is a
20 CMC section a new drug application, public
21 information.

22 A What is your question?

23 Q I will ask it a third time. Is the
24 CMC section of a new drug application public
25 information?

1 A CMC section shouldn't be public
2 information.

3 Q So I am trying to understand your
4 testimony under oath that you've seen and been
5 provided with the NDA for Diovan. Where did you get
6 it?

7 A I said I have reviewed. I didn't say
8 I've seen it. I said I have reviewed a lot of
9 documents, you know, from different manufacturers,
10 perhaps including Novartis' procedures, but
11 Novartis' procedures and chemical manufacturing
12 procedures has been disclosed in their patents.
13 It's been published. There's plenty of literature
14 on it.

15 Q So if I hear what you're saying now
16 and if we're looking for honest, forthright
17 testimony, it sounds like you don't know whether
18 you've seen the NDA for Diovan, correct?

19 MR. NIGH: Form objection.

20 A I don't know if I've seen it.

21 Q All right. In your career, sir, have
22 you ever prepared an abbreviated new drug
23 application seeking to obtain FDA approval to market
24 any generic equivalent drug product?

25 A In my career I have been involved in

1 many IND filings, CMC sections of IND, CMC sections
2 of NDA, ANDA for my clients, not specifically for
3 any of my own specific products.

4 Q My question was have you ever been
5 involved in preparing --

6 A Yes, I have.

7 MR. NIGH: Hold on. Dr. Najafi. Wait
8 until he finishes his question.

9 A Sorry.

10 MR. NIGH: And then answer. We're
11 getting --

12 MR. TRISCHLER: Sorry, Dan.

13 Q What abbreviated drug applications did
14 you prepare and submit to the FDA?

15 A Confidential.

16 Q For what drugs?

17 A For drugs that -- from our clients'
18 drugs.

19 Q Tell me the names of the drugs. The
20 active pharmaceutical ingredients are not
21 confidential.

22 A I can not recall right now. Also,
23 it's client-specific and a lot of our clients don't
24 want to have their names disclosed.

25 Q I haven't asked your client's names.

1 A I know.

2 Q Sitting here today providing -- let me
3 finish before you start.

4 Sitting here today providing testimony under
5 oath, you can't name one drug product where you were
6 involved in submitting the abbreviated new drug
7 applications for its generic formulation, right?

8 A I cannot recall.

9 Q Have you ever worked in regulatory
10 affairs for a generic drug manufacturer?

11 A No.

12 Q Have you ever --

13 A I have not worked in regulatory
14 affairs for any generic manufacturers.

15 Q Have you ever worked or been employed
16 by the FDA?

17 A I have never been employed by the FDA.

18 Q Have you ever -- are you familiar with
19 the Center for Drug Evaluation and Research, CDER?

20 A I have attended many meetings at CDER.

21 Q Have you ever worked with CDER where
22 you've had responsibility for evaluating new drug or
23 new drug applications?

24 A I have not been involved with CDER.
25 You should restate your question.

1 Q I should or you need me to?

2 A Please restate your question.

3 Q Have you ever worked with CDER where
4 you had responsibility for evaluating new drug or
5 abbreviated new drug applications?

6 A I have not worked with CDER in
7 evaluating any new drug application.

8 Q Have you ever been retained as a
9 consultant by FDA office of generic drugs to assist
10 in evaluating any portion of an abbreviated new drug
11 application?

12 A I have not been involved in generic
13 drug division of the FDA.

14 Q And I think it's Section 4 of your
15 report -- your declaration you describe FDA
16 expectations and requirements for generic drug
17 manufacturers. Do you recall that?

18 A Could you show it to me?

19 Q Sure.

20 A Put it on the screen.

21 MR. TRISCHLER: It's Exhibit 1. Can
22 you put it up, please.

23 A Highlight it.

24 Q Can you flip through it? I think it's
25 section 4. I think it starts on page 5, maybe, if I

1 recall correctly. There we go. Do you see that?

2 A Yes.

3 Q And as I was saying, this is the
4 section of your report where I think you proceed to
5 describe what you consider to be the expectations or
6 some of the expectations and requirements for a
7 generic drug manufacturer, right?

8 A Mm-hmm.

9 Q Is that "yes"?

10 A Yes.

11 Q The fact of the matter is, though,
12 Doctor, that you're never had personal
13 responsibility for synthesizing API that was used
14 for generic drug formulation, correct?

15 A I have not had responsibility in
16 synthesizing an API for a generic drug manufacturer,
17 but I have been involved in, you know, drug
18 development and I've been involved with lots of
19 FDA-related activities and the spirit of what I have
20 put in is if and when you change the chemical
21 process, if you make lasagna by following step one,
22 step two, step three, and if you change that and you
23 create your own recipe, you have responsibility to
24 do proper due diligence to look at structural
25 molecules that give you structural clue to

1 protection problem and you need to disclose that to
2 the FDA and you need to do proper due diligence and
3 effectively look for those, you know, potential
4 problem and look for genotoxic compounds and report
5 it.

6 Q Have you ever developed a synthetic
7 process used for the API of a generic drug
8 formulation?

9 A I have developed synthetic process of
10 hundreds of molecules in my time and I continue to
11 develop processes for hundreds of molecules, but not
12 for a generic drug, but I can assure you I
13 understand the synthesis synthetic procedure of
14 valsartan.

15 Q Have you ever had oversight
16 responsibility for manufacturing a generic drug
17 product?

18 A No. I have not had oversight
19 responsibilities for a synthesis of a generic drug
20 product or drug substance, but I've had
21 manufacturing responsibilities for lots of synthetic
22 molecules in large scale at my previous company,
23 Aldridge Chemical, at Rhone-Poulence
24 Pharmaceuticals, et cetera, and NovaBay.

25 Q Have you ever prepared a drug master

1 file in connection with an API for a generic drug?

2 A Not personally.

3 Q In the notes of deposition that
4 brought us here today, I asked you to provide
5 certain materials to me at the time of the
6 deposition. One of the things I asked for were any
7 and all papers that you prepared on the topic of
8 drug safety and cancer risk. Do you remember seeing
9 that request in the notice?

10 A Yes, I have.

11 Q I did not receive any papers or
12 publications on those topics, so I have to assume
13 that you have never published on those issues.
14 Would that be a fair assumption on my part?

15 A I have not published on anything, any
16 genotoxic compound, nitrosamines except the citizen
17 petition which we filed with the FDA regarding
18 nitrosamine which FDA corroborated 100 percent, and
19 I've also presented at a generic manufacturing
20 symposium where my audience was a whole huge number
21 of generic manufacturing people.

22 Q I appreciate that, but my question was
23 a little broader than that. I had asked for all
24 papers and publications prepared on the broader
25 topic of drug safety and cancer risk. Have you ever

1 published on those topics?

2 A I haven't published on those topics
3 and what I can -- you know, there are lot of
4 publications. That's really a toxicologist and
5 epidemiologist sort of activity. I rely on them.

6 Q And what you were answering on the
7 topic of nitrosamines what you told me is that
8 you've not submitted any peer-reviewed publications
9 on the issue of nitrosamines and drug products,
10 correct?

11 A So what's your definition of peer
12 reviewed?

13 Q My definition of peer review would be
14 a publication in a scientific journal that is
15 reviewed by scientists in the field for accuracy,
16 quality and reliability of methods prior to the time
17 that it's published.

18 A Our citizen physician, my citizen
19 petition for ranitidine Zantac meets those
20 criterias, so under that circumstance it is peer
21 reviewed.

22 Q So you consider a citizens petition to
23 be a peer-reviewed publication?

24 A Absolutely.

25 Q Who can submit a citizens petition?

1 A Anybody can submit a citizen petition.

2 Q If I sent a citizens petition saying
3 Dr. Najafi's declaration in this case is unreliable,
4 has that been peer reviewed?

5 A You can certainly do that and it will
6 be peer reviewed by FDA scientists and they will
7 then respond to you that Clem, you're wrong.

8 Q In formulating the opinions that are
9 contained in this declaration that we're looking at
10 now, did you review any internal Mylan documents?

11 A In formulating this last declaration,
12 I don't believe so.

13 Q Did you review by ZHP documents?

14 A I have reviewed both Mylan and ZHP
15 documents months ago but not in formulating this
16 declaration.

17 Q And if I ask the same question for the
18 other manufacturer defendants to this litigation:
19 Teva, Aurobindo, Hetero, Torrent; have you reviewed
20 any of their documents?

21 A I have reviewed. I've spent hours and
22 hours looking at their manufacturing issues, looking
23 at their, you know, all of that, but not for this,
24 you know, putting this declaration together.

25 Q So in terms of those two core opinions

1 we talked about, you don't plan to -- you're not
2 relying upon and did not consider any of the -- any
3 internal documents from any of the manufacturers?

4 A I did not, no.

5 Q I asked you before if you reviewed the
6 new drug application for Diovan and you said you
7 could not. Just for completeness sake, do you know
8 if you ever reviewed the new drug application for
9 Exforge or Exforge HCT?

10 A I cannot recall. I believe I've
11 reviewed a lot of the defendants' material. I might
12 have reviewed some of the publicly available
13 information on the work Ciba-Geigy did which led to
14 Diovan.

15 I've looked at their patents. I've looked at
16 their procedures, their recipes, their synthesis,
17 published data, a lot of that. I have looked at a
18 lot of documents over the last year and a half or so.

19 MR. TRISCHLER: Let's take a break,
20 please. I want to look at some notes and see what I
21 want to do next.

22 MR. NIGH: Take a ten minute break?

23 MR. TRISCHLER: Sure.

24 THE VIDEOGRAPHER: The time is 2:22.

25 This concludes Media No. 4.

1 (A recess was taken.)

2 (After the recess the following
3 occurred:)

4 THE VIDEOGRAPHER: The time is now
5 2:48. This begins Media unit 5. You may proceed.

6 BY MR. TRISCHLER:

7 Q Doctor, I just have a few other things
8 I want to cover with you. One of the documents that
9 was in your file that I was provided with was a
10 chart entitled "valsartan products not currently
11 recalled." Are you familiar with that chart?

12 A Would you bring it up so we can be
13 looking at the same thing?

14 Q Sure.

15 MR. TRISCHLER: Frank, are you able
16 to -- it was not in the group of exhibits that I
17 premarked. Are you able to pull it up, Frank, and
18 get it in front of the witness?

19 MR. STOY: Yes. Let me try to find it
20 here. I am going to attempt to share my screen. Is
21 this the document?

22 MR. TRISCHLER: Yes, that's it. Thank
23 you, Frank. I guess we will have this marked as an
24 exhibit and sent to the reporter through the chart,
25 but whatever the next numbered exhibit is.

1 THE VIDEOGRAPHER: That will be 29.

2 MR. TRISCHLER: Thank you.

3 BY MR. TRISCHLER:

4 Q Doctor, can you see this Exhibit 29?

5 A It is very tiny. Yes, I do.

6 Q It's a 15 page document. At the top
7 it says "valsartan products not currently recalled"
8 dated September 21, 2015, and it was provided to me
9 by your counsel as part of your file. Do you recall
10 that?

11 A Yes.

12 Q And if I understand correctly this
13 would be a list of valsartan products, marketed and
14 sold in the United States that were not subject to
15 any recall at least as of September 2018, right?

16 A I believe so.

17 Q And you had mentioned earlier that
18 under the valsartan recalls, products were recalled
19 if they had NDMA content above 96 nanograms per
20 milliliter, right?

21 MR. NIGH: Objection. Go ahead.

22 Q You can answer.

23 A Ninety-six nanograms dosage you end up
24 consuming per day.

25 Q The limit for NDEA, there was a

1 separate limit for NDEA, right?

2 A I think NDEA was far lower, maybe 12
3 or 20, something like that.

4 Q Does 26.5 sound right?

5 A Yes.

6 Q And so if valsartan products were
7 tested and the limits observed were above those
8 levels of 96 nanograms for NDMA and 26.5 nanograms
9 for NDEA, they were recalled, is that your
10 understanding?

11 A That's my understanding.

12 Q And so this list would be a list of
13 products that had NDEA content of either zero or
14 less than 96 or somewhere in between?

15 A Right.

16 Q And these would be -- this list that
17 we will mark as Exhibit 29 is a list of product that
18 would have been tested and had NDEA content of
19 either zero or 26.5 or something in between.

20 A Right.

21 Q To your knowledge, have you
22 independently tested any of these
23 valsartan-containing medications that appear on this
24 Exhibit 29?

25 A I have not. I'm not prepared in this

1 meeting to to take a look at these and compare it
2 with what we have or have not listed, because I'm
3 just -- I don't have the documentations in front of
4 me to tell you what got tested and what didn't.

5 Q Okay, but based on what we know right
6 now, all of the drug products listed on Exhibit 29
7 may very well have had some NDMA or NDEA in the
8 product, it was simply below the limit established
9 by FDA?

10 A That's what FDA has obviously done.
11 They have made those determinations based on this
12 interim level, interim level which is 96 or
13 20-something nanograms of NDEA.

14 Q So as far as we know, every drug
15 listed on Exhibit 29 had some NDMA or NDEA in it,
16 right?

17 A As far as I can tell you, I have no
18 knowledge of what the exact numbers of NDMA or NDEA
19 is in any of these products. All I can attest to is
20 that they were not recalled by the FDA.

21 Q And so you cannot rule out the
22 possibility that every drug listed on Exhibit 29 had
23 some NDMA or NDEA?

24 A I cannot rule out. Let me just
25 restate my position. I believe no NDMA or NDEA

1 should be allowed in any valsartan product, period.
2 Zero. So if they contain NDMA and NDEA and FDA is
3 allowing it above certain limit, that's FDA's
4 prerogative, but in my expert opinion, no NDMA or
5 NDEA should be allowed.

6 I am not a toxicologist, but I know something
7 about the chemistry of NDMA and the fact that it
8 comes a methylating agent, and methylating agents are
9 a fantastic cancer causing agent.

10 MR. NIGH: Dr. Najafi, make sure you
11 let him finish his question before you answer.

12 THE WITNESS: My apologies.

13 Q The limits established by FDA that
14 you've referenced --

15 A Right.

16 Q -- 96 nanograms per millimeter for
17 NDMA, that limit remains in effect to this day, does
18 it not?

19 MR. NIGH: Object to form.

20 A As far as I know, FDA currently is
21 accepting 96 nanograms as an interim sort of level,
22 but their goal is going to be zero and their goal is
23 going to be basically FDA -- I'm reading from FDA's
24 guidance. It says FDA advises that nitrosamines
25 should be absent, not detectable for ARBs, API or

1 ARB product period, stop. It's been cited in my FDA
2 general advice document which is actually cited in
3 my report.

4 Q All I asked you was that the limit of
5 permissible NDMA content of 96 nanograms per
6 milliliter remains in effect to this day.

7 A As far as I know, 96 nanograms remains
8 in effect and is acceptable today, but may not be
9 acceptable tomorrow.

10 Q And the 26.5 nanograms limit for NDEA
11 remains in effect to this day?

12 A As far as I can tell, that remains as
13 an interim acceptable level today but, again, their
14 guidance says they are going to go to zero. So I am
15 answering your question.

16 MR. TRISCHLER: All right. I have no
17 further questions of the witness at this time. I do
18 think that there are documents that we have
19 requested that have been -- excuse me, documents
20 that have been identified worked on by this witness
21 that were identified during the course of this
22 deposition that are relevant to the witness that
23 have been disclosed in this case and that the
24 witness has been offered.

25 I am going to reserve the right to

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1 bring a motion on that issue to obtain those
2 documents and those records and to redepose the
3 witness on those issues, but for now I don't have
4 any further questions, although I believe there may
5 be a few other people on my side that have some
6 followup.

7 MR. NIGH: Mr. Trischler, I am going
8 to put my position briefly. I think at this point
9 we've gone over four hours of record time which is,
10 in many of these questions, have been far outside of
11 the scope. And the vast majority of documents, if
12 there are any, we presented those objections 48
13 hours ago and do not believe there is a basis to
14 come back for this deposition.

15 In addition, I'm surprised that it's
16 even gone four hours, but it sounds like it's going
17 to go even further and so I don't even know if there
18 will be any time at the end of this. And to the
19 extent that there is an argument being raised of
20 missing documents, really, the timing here has just
21 gone far longer than we think was necessary. That's
22 my position.

23 CROSS-EXAMINATION

24 BY MR. GISLESON:

25 Q Good afternoon, Doctor. My name is

1 John Gisleson and I represent Aurobindo.

2 MR. GISLESON: If we could go back
3 please, Bill, and pull up Exhibit 17, which is the
4 valsartan USP monograph.

5 Q So, Doctor, in your career to what
6 extent have you utilized USP monographs in your
7 work?

8 A We use it almost every day, every week
9 at Emery Pharma to effectively follow, you know, and
10 release drug product and drug substance at Emery.

11 Q To your knowledge are the USP
12 monographs utilized in connection with
13 manufacturing?

14 A USP monographs are utilized in
15 connection with manufacturing, yes.

16 Q Do you know whether the FDA relies at
17 all on USP monographs?

18 A To some extent they do. FDA and USP
19 have sort of a tangential relationship with the USP.
20 USP is an independent company and it was formed 200
21 years ago for the purpose of, essentially,
22 standardizing our drug supplies and trying to
23 develop a standardized quality system for the drug
24 on the market.

25 Q Do you have an understanding as to how

1 FDA utilizes USP monographs?

2 A Can you be specific? You know, what
3 do you mean by to what extent FDA utilizes?

4 Q Do you have an understanding as to how
5 FDA utilizes USP monographs?

6 MR. NIGH: Objection. Form.

7 A USP primarily works with the sponsor
8 of the innovators to get the -- you know, basically
9 to get the drug, the generic drugs, you know,
10 effectively easing the generic drug availability.

11 So, for example USP toward the end of the drug
12 patent, USP contacts the brand and says "share with
13 me your protocol. Share with me your standard.
14 Share with me your impurities," and the drug -- the
15 brand usually does that. If they don't do it, USP
16 develops its own standards and then everybody has to
17 meet that minimum standard.

18 Q In your experience, are the USP
19 standards reliable for manufacturers?

20 MR. NIGH: Form objection.

21 A Could you repeat your question?

22 Q Sure. In your experience, are USP
23 monographs accurate in their prescription of the
24 drug products addressed in the monographs?

25 MR. NIGH: Form objection.

1 A In terms of reliability, it's a
2 minimum standard that you have to meet, but we often
3 go above and beyond USP.

4 Q And in your experience, are the USP
5 monographs reliable in terms of the accuracy of the
6 information that they contain?

7 MR. NIGH: Objection.

8 A In my experience, USP monograph is the
9 starting point for, you know, for basically looking
10 at the impurity profile.

11 Q And if we look at Exhibit 17, does
12 this identify specific impurities that have been
13 found in the valsartan product?

14 A They do.

15 Q What are the specific impurities that
16 are identified there?

17 A There are a couple of impurities
18 listed; impurity A, impurity B, but in fact there
19 are more impurities.

20 Q Do you have an understanding why,
21 then, the USP monograph didn't identify all
22 impurities?

23 MR. NIGH: Form objection.

24 A We often find other impurities and we
25 bring it to the attention of the sponsor and show

1 them that these impurities need to be identified or
2 if the levels are -- meet certain standards, they
3 need to be identified or they need to be, you know,
4 purified, tested, quantified. Really, there are
5 different standards, but no, USP -- how can I say
6 it, it's really just -- it's really an entry point,
7 you know. It's really a starting point. It's a
8 guidance.

9 Q In your experience are USP monographs
10 updated from time to time?

11 A I believe they are.

12 Q In your experience, when USP
13 monographs are updated, would they also include
14 additional impurities that weren't previously known?

15 A They often do, but they are very slow
16 in doing that. A company such as ours would
17 actually need to contact USP and say, hey, we
18 actually found additional impurities, you know, you
19 should list that and it might take them a couple of
20 years to bring that up and do their own testing and
21 corroborate and all of that and then it might get
22 into that, you know it might get into sort of USP
23 monograph.

24 Q And in your experience it's good
25 practice when new impurities are identified to

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1 report those impurities to the FDA; is that right?

2 A Absolutely. Reporting them to USP is
3 a good practice. If it's a genotoxic compound, I
4 think you want to make an more urgent case reporting
5 it to the manufacturer, reporting it to the USP,
6 reporting it to the FDA in the case of, for example,
7 sartans or ranitidine, Zantac and others.

8 Q Does the -- and we'll look at
9 Exhibit 17 specifically. Does this USP monograph
10 identify how to test for impurities?

11 A This USP monograph does provide you
12 with a basic methodology to identify some of the
13 impurities.

14 Q What is the methodology that's
15 identified on this USP monograph?

16 A Thank on hang on a second. There
17 is -- to identify impurities you have to go through
18 set up either HPLC or gas chromatography, various
19 instrumentation and set it up, set up the instrument
20 and run it according to the basic principle that USP
21 lays down.

22 Q What are the specific tests or tests
23 that are identified in this USP monograph for
24 testing for the presence of impurities?

25 A So they use -- basically to assess

1 impurity profile, they are using chromatographic
2 technique. Chromatographic technique means --
3 meaning in this case high pressure liquid
4 chromatography and that's it.

5 Q If we look under the impurities
6 section on this first page, there's a reference to
7 chromatographic system, see chromatography 621
8 system suitability and then it has mode LC detector
9 UV 230 NM.

10 So what is the information that provides to a
11 manufacturer as to how to test for an impurity?

12 A You're getting fairly technical here.
13 I don't know whether this is useful for this
14 conversation, but the HPLC is an instrument that
15 there are pumps attached to it. The pumps are
16 pushing. There are two pumps pushing some vents
17 into a column. There's solvent A, solvent B, and
18 depending on what's in the solvent A and B, the
19 column gets conditioned so that the column is a
20 stationery phase. And so the separation happens
21 through the HPLC column and then it goes through a
22 detector and then that detector would be, you know,
23 UV detector. It could be, you know, CHAD detector
24 which stands for charge aerosol detector. It could
25 be ELT detector. It could be a mass spec detector.

1 So it goes through the detector and comes out
2 and out of that detector. So any UV active compound
3 gets detected. So in this case they are looking at
4 for UV active compound.

5 Q How much -- I'm sorry. Continue. Are
6 nitrosamines UV active compounds?

7 A Nitrosamines are not UV active
8 compounds. So they become invisible, so UV.

9 Q Using the chromatographic system with
10 liquid chromatography and a UV detector, in your
11 experience is that capable of identifying
12 nitrosamines?

13 A In my experience you have detectors
14 are not capable of detecting nitrosamines.

15 Q Does this USP monograph identify that
16 a manufacturer should use gas chromatography, mass
17 spectrometry to test for the presence of nitrosamine
18 impurities?

19 MR. NIGH: Form objection.

20 A So this specific monograph does not
21 provide you with the, you know, HPLC mass spec
22 detector detection.

23 However, you know, the chemist and the
24 synthetic chemist who is involved with the synthesis
25 of the drug should consider, you know, methods that

1 do not -- that can potentially show the none UV
2 active compound such as nitrosamine and use of mass
3 spec. For example, HPLC connected to a mass spec or
4 GC connected to a mass spec, that's been around since
5 I was an undergraduate in 1979.

6 Q How many to your knowledge -- strike
7 that.

8 What drugs prior to June 2018 were found to
9 contain nitrosamine impurities?

10 MR. NIGH: Form objection.

11 A To my knowledge, you know, the drugs
12 that contained nitrosamine impurities, perhaps not
13 known to me. That doesn't mean that it exists, but
14 nitrosamines have been around since 1970s and
15 knowledge of NDMA has been around since 1970s and
16 WHO has been warning drug companies to look for NDMA
17 through various guidances regarding nitrosamine.

18 And ICH M7 guidelines specifically mentions
19 nitrosamine as the drug of concern as they have -- as
20 the impurities of concerns as a mutagen of concerns.
21 So just because they haven't been shown before 2018
22 doesn't, you know, basically give these guys a pass.

23 Q You said that you were familiar with
24 current good manufacturing practices. Are you aware
25 of any current good manufacturing practice that

1 existed in or before June 2018 that required a
2 manufacturer to test for nitrosamine impurities in
3 pharmaceutical products?

4 A In current and good manufacturing
5 practices really refers to using the latest
6 technology and in looking for impurities, making
7 sure your drug is safe.

8 And this is exactly to the point I was trying
9 to make earlier, that basically the USP monograph is
10 really just opens the door to you. So this is a
11 common mistake and I also mention that in my
12 presentation to this symposium that I was presenting
13 regarding which is online, actually. You know,
14 companies need to be looking for structures of
15 concern which is mentioned in ICH M7, and those
16 structures of concern should actually give you sort
17 of a window toward compounds you should be looking
18 for.

19 Q Can you identify any publication that
20 was issued before June 2018 that advised
21 pharmaceutical manufacturers that testing for
22 nitrosamines was part of current good manufacturing
23 practices?

24 MR. NIGH: Form objection.

25 A I can refer you to international

1 committee to -- IRAC. It's a part of WHO that
2 specifically warns the manufacturers to look for
3 nitrosamines and there is a specific test that they
4 ask a lot of manufacturers to do which is called --
5 basically it's called NAP testing, N-A-P testing,
6 which in fact they encourage manufacturers to test
7 their compounds to see if it's prone to developing
8 nitrosamine. And you can look that up under NAP
9 testing or basically WHO testing for nitrosamine
10 and -- nitrosamine and NDMA.

11 Just one second. I actually have somebody
12 here. I have to give them the key to my car.

13 MR. NIGH: Let's take a quick break.

14 MR. GISLESON: Okay.

15 THE VIDEOGRAPHER: Time is 3:18. We
16 are going off the video record.

17 (A recess was taken.)

18 (After the recess the following

19 occurred:)

20 THE VIDEOGRAPHER: The time is 3:18.

21 We are back on the video record.

22 BY MR. GISLESON:

23 Q Did the FDA ever issue any guidance
24 like what you have just described from that
25 international organization?

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1 A Has FDA ever issued any guidance
2 regarding NDMA or nitrosamine?

3 Q Similar to the international guidance
4 you just identified.

5 A Post 2018 or pre 2018?

6 Q Pre 2018.

7 A I don't know, honestly.

8 Q You received an envelope and I think
9 you started to open it earlier that contained some
10 documents that we sent to you.

11 A Right.

12 MR. GISLESON: Bill, it's the document
13 behind Tab 6. It's a USP monograph, this one for
14 valsartan and --

15 THE WITNESS: Should I open it?

16 MR. GISLESON: Please.

17 THE VIDEOGRAPHER: For the record, it
18 would be marked as Exhibit 30.

19 Q Doctor, it's behind Tab 6.

20 MR. NIGH: Mr. Gisleson, how am I
21 getting a copy of this document?

22 MR. GISLESON: It's in the Exhibit
23 File Share, Paul.

24 MR. NIGH: Okay. Okay. Tab 6. I see
25 it now.

1 Q Have you, Doctor, reviewed the USP
2 monographs for all the different valsartan products
3 that are at issue in this lawsuit?

4 A I have reviewed a number of them, yes.

5 Q And have you also reviewed the USP
6 monograph for the valsartan hydrochlorothiazide
7 tablets?

8 A Yes, I believe so.

9 Q Looking at Exhibit 30, is it correct
10 that you have reviewed this USP monograph
11 previously?

12 A This is --

13 Q Tab 6.

14 A Tab 6? Okay. Okay. I need a
15 refresher. Just give me a second.

16 Q No problem.

17 A Okay. I scanned through it. Go ahead
18 with your question.

19 Q So this USP monograph became effective
20 as of May 1, 2015; is that right?

21 A Okay.

22 Q Looking at the upper left-hand corner
23 of the first page.

24 A Uh-huh.

25 Q Is that correct?

1 A Yes, May 2015.

2 Q And then if you can go to the section,
3 please, on impurities which I believe is the third
4 or actually the fifth page.

5 A Okay. Yes. I'm on it.

6 Q Thank you. Does this identify
7 specific impurities that had been identified in the
8 valsartan and hydrochlorothiazide tablets?

9 A It looks like it, yeah.

10 Q And what were the specific impurities
11 that were identified?

12 A There is hydrochlorothiazide,
13 benzothiadiazine related compound A. There's
14 hydrochlorothiazide RS; there's USP valsartan RS;
15 there's USP valsartan related compound and so forth.

16 Q To your knowledge are there any health
17 effects or health hazard associated with those
18 impurities?

19 MR. NIGH: Form objection.

20 A I don't know.

21 Q Then this also shows that there are
22 acceptance criteria for those impurities that allow
23 them to be present in the finished drug product at
24 certainly no more than percentages; is that correct?

25 A Right.

1 Q When it says in here that NMT
2 0.2 percent of any other impurity excluding
3 valsartan-related compound A, does that include
4 unidentified impurities?

5 MR. NIGH: Form objection.

6 Q Let me rephrase the question. Do you
7 have an understanding of what's meant by not more
8 than 0.2 percent of any other impurity?

9 A Yes.

10 Q What does that mean?

11 A So it means there are other
12 unidentified impurities potentially that should not
13 be more than .2 percent, not more than .2 percent in
14 the chromatogram.

15 Q Does this monograph identified the
16 testing procedure that a manufacturer should use to
17 identify any impurities for this
18 valsartan-containing drug?

19 A So, basically, again, it goes back to
20 this question the whole concept that I tried to
21 explain with Clem. There are impurities that -- you
22 could have up to maybe a hundred different
23 impurities, John, in valsartan in this chromatogram,
24 hundred little peaks, right?

25 You can't identify. You can't tell which one

1 is which. You just go after picking up a few of
2 them, you know, and USP effectively provides those
3 impurities as reference standards and so forth, but
4 it's really the duty of the manufacturer to look at
5 the drug synthesis and identify and look for their
6 structural entities of concern.

7 You know, for example, when I look at a
8 molecule, John, when I look at c double bond o, c
9 carbon and chlorine, I know this chloromethyl ketone
10 is like a tear gas. It's going to burn your eyes.
11 If I see a molecule that has nitrite in it, I'm going
12 to say "Oh, shit. This is going to --" pardon my
13 language -- "this is going to be created
14 nitrosamine."

15 So when you look at these types of -- you
16 know, this is like the recipe that USP gives you is
17 more or less like a TikTok video cookbook. Have you
18 seen these TikTok videos that give you direction on
19 how to make, you know, a certain dish? This is a
20 TikTok video. So what you need to do is you need to
21 do your own due diligence. You can talk to any
22 chemist. At my company or at any other company, they
23 tell you this is just an entry level stuff.

24 So it's the duty of the organic chemist at the
25 company, synthetic organic chemist to say there are

1 structural concerns in my recipe and I am worried
2 about this impurity; therefore, look into it, okay.
3 So, this is very little and you cannot just say here
4 is TikTok video, you know, are you going to be able
5 to do this. You can't. And in fact every -- this is
6 just a starting point.

7 Q So when this refers to acceptance
8 criteria no more than 0.2 percent of any other
9 impurity, the manufacturer is to add up the
10 different unidentified impurities to determine
11 whether the total amount exceeds 0.2 percent?

12 A It means you could have lots of little
13 impurities as long as they are not over a certain
14 level, as long as they are not over .2 or
15 .1 percent, but you also need to consider if these
16 impurities are growing or not as a function of time.

17 Often we get a call from a frantic
18 manufacturer that says my drug is on the market and
19 we have -- we got report from our retained testing
20 that our drug is producing an impurity and we need to
21 figure out what that impurity is, and they tell us
22 drop everything, work on this, figure out what this
23 impurity is, you know, and we've been doing -- we
24 have done this.

25 So this is -- just to show me a few impurities

1 here, I can assure you if you look at some of the
2 chromatograms of valsartan or this, the one that
3 you're showing me, there are going to be many, many,
4 many different impurities in the chromatogram.

5 Q What is the testing method in this
6 monograph that a manufacturer should use to
7 determine whether there are any impurities?

8 A They need to follow current good
9 manufacturing practices and the current, you know
10 has -- you know, it means you gotta LCMS. HPLC
11 alone, it is a 1960's technology and unfortunately
12 FDA has been very lax about it and we've had
13 discussions with them. And companies are saying we
14 can't afford LCMS. Are you kidding me?

15 Q What is the testing method identified
16 in this specific monograph for how a manufacturer
17 should test for impurities?

18 A The testing method they are
19 identifying is HPLC with UV detector.

20 Q Is that shown on the prior page?

21 A Yeah.

22 Q Under chromatographic system?

23 A Yes.

24 Q Can you go to the prior page, please?

25 A Yeah, I am looking at it. Yeah. It's

1 UV.

2 Q And it says chromatographic system?

3 A Yes.

4 Q See chromatography 621 system
5 suitability mode LC detector UV.

6 A You see the detector is UV, which
7 means it's ultra violet detector. So in my opinion,
8 USP is not following CGMP. USP is behind time and
9 these companies are hiding behind USP and I think
10 they are violating FDA's current good manufacturing
11 practices. And I have mentioned this to, you know,
12 drug manufacturers, the generic people as well and
13 they agree. I've had conversations with many of
14 them.

15 Q The test that's identified here, the
16 chromatographic system using the LC mode with a UV
17 detector, that test is the starting point, you said,
18 for what a manufacturer should do to test for
19 impurities?

20 A Exactly.

21 Q And that test does not identify
22 nitrosamine impurities, does it?

23 A No, it doesn't. You could have a lot
24 of nitrosamine in this compound and this LC test
25 will not show it. It will be invisible.

1 Q So it's your opinion, as you said,
2 that none of the defendants' valsartan products
3 should have contained any NDMA or any NDEA; is it
4 correct that you believe FDA is wrong in permitting
5 the defendants' valsartan products to be sold so
6 long as they are -- they have less than 96 nanograms
7 of NDMA or 26.5 nanograms of NDEA?

8 MR. NIGH: Form objection.

9 A John, I cannot comment for FDA, but I
10 have stated this in our previous conversations as
11 well. I believe the levels of NDMA and NDEA should
12 be zero. These are mutagenic DNA reactive molecules
13 that knocks the hell out of your DNA, and in fact
14 the NDMA is used to create cancer in laboratory
15 animals.

16 Q So your opinion, then, directly
17 contradicts the FDA's determination that patients
18 may use the defendants valsartan products so long as
19 they contain less than either 96 nanograms of NDMA
20 or 26.5 nanograms of NDEA, correct?

21 MR. NIGH: Form objection.

22 A I'm going to reiterate what I said,
23 John. I believe in zero NDMA and NDEA. I think
24 FDA's thinking is also zero NDMA, NDEA. In my
25 opinion, perhaps maybe it's because it's political,

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1 I don't know, but you're asking my opinion. I
2 cannot speak on behalf of FDA. I told you what I
3 think.

4 Q All right. Your opinion contradicts
5 the FDA's determination that these valsartan
6 products can be sold to and consumed by patients so
7 long as the nitrosamine levels are less than the
8 accepted intake levels identified by the FDA,
9 correct?

10 MR. NIGH: Form objection. Hold on.
11 Form objection. Mischaracterizes testimony. It's
12 been asked and answered multiple times.

13 MR. GISLESON: It's been asked. It
14 hasn't been answered.

15 MR. NIGH: It has been answered. It's
16 just not the way you want it answered.

17 Q Your opinion directly contradicts what
18 the FDA has said; namely, the defendant's products
19 can be sold to and consumed by patients so long as
20 the nitrosamine levels are less than the FDA's
21 determined acceptable intake levels or limits?

22 A So --

23 MR. NIGH: Form objection. Asked and
24 answered. Mischaracterizes testimony.

25 A John, I have already mentioned what's

1 my opinion. I have also and FDA has also made its
2 ruling. FDA is saying 96 nanograms is the interim
3 level, but FDA in their most recent filing which
4 is -- I'd like to quote you my -- the FDA guidance
5 which is called FDA general advice and I'd like to
6 actually make -- put that as part of the record if
7 you could -- I don't know. It's page 1 and it's
8 paragraph number -- it's page 1, paragraph 2 of
9 background. I'd like to make that as part of the
10 record and I'd like to read it that to you.

11 It says, "Due to their known potent
12 carcinogenic effect and because it is feasible to
13 limit these impurities," because it's feasible to
14 limit these impurities "by taking reasonable steps,"
15 meaning chemical synthesis, chemical synthetic steps
16 "to prevent or eliminate their presence, FDA has
17 determined that there is no acceptable specification
18 for nitrosamine in ARBs, API or drug product."
19 Period. Full stop.

20 This is FDA. If you want to misquote me, you
21 can go ahead and do that but, please, when you do,
22 make sure you put this next to it. Therefore, FDA
23 goes on and says, "FDA advises that nitrosamines
24 should be absent in practices; i.e. not detectable as
25 described below from ARB API and API brought

1 product," should be absent.

2 This is the key thing. As an initial measure,
3 FDA published levels of impurity exceeding these
4 interim levels recommended for recall before the
5 market. So they said they recommended anything above
6 certain level to be recalled, but their goal is zero.
7 Zero. I hope I've answered the question.

8 Q Doctor, what's the date of the
9 document you just read from?

10 A The date of this document? Let me
11 look it up. It's part of the submission of the -- I
12 don't know. I think that's for you guys to figure
13 out. This was -- there is no date on it.

14 Q Can you show us the first page of the
15 document, please, on the camera so we can see what
16 it says? It looks like it's a letter from the
17 Department of Health and Services.

18 A Is this part of the record? I think
19 that was submitted.

20 Q No, because I didn't offer it and I've
21 never seen it before.

22 A It was part of my testimony. It's
23 there.

24 Q Even with the presence of NDMA or
25 NDEA, do the defendant's valsartan products still

1 lower blood pressure in adults and children who
2 still use the products?

3 MR. NIGH: Form objection.

4 A John, you want my honest opinion? I
5 don't know. I don't know, because there is no
6 doubt -- I have no doubt that there is valsartan
7 molecule there, but I have no idea what the
8 interaction of NDMA, NDEA at those high levels could
9 be, because I consider NDMA and NDEA as an active
10 compound.

11 A lot of the impurities that you saw in the
12 USP monogram, a lot of the excipients: The sugar,
13 the magnesium citrate and various just binding agent
14 that makes them feel inactive, nitrosamines are
15 extremely active and so I don't know whether actually
16 they will help or hurt or they will cause certain --
17 you know, bind something to some receptors.

18 I'm not a toxicologist. I'm not a physician
19 to know, but that's for another expert to comment.

20 Q Have you done any analysis as part of
21 your work in this case to determine whether NDMA or
22 NDEA interferes with the chemical ability of
23 valsartan to perform its intended purpose of
24 lowering blood pressure and of reducing
25 hospitalization for heart failure?

1 A We have not done any testing that
2 shows that in DNA inhibits the effectiveness of
3 valsartan or promotes its effectiveness of valsartan
4 or any of that. We have not done any of those
5 tests.

6 Q And you also didn't do that testing
7 for NDEA to determine whether it had such an effect,
8 correct?

9 A We have not done any testing to show
10 whether NDEA promotes the pharmaco dynamics of the
11 drug or actually inhibits the pharmaco dynamics of
12 the drug. You could actually increase the activity
13 of the valsartan or reduce its activity, any of
14 those things. I don't know. We haven't done any
15 testing. Nobody has asked us. Plaintiffs' lawyers
16 have not asked us to do any of that.

17 Q Nor have you used your knowledge and
18 experience simply to analyze without testing whether
19 NDMA or NDEA interferes with the ability of
20 valsartan to function as intended according to the
21 label?

22 A We have not done any of those testings
23 and it's not part of our plan to do any of those
24 testings.

25 Q Are you familiar with the phrase

1 compendial standards?

2 A Yes, I am.

3 Q To what does that refer?

4 A Compendial standards are standards,
5 basically official quality standards used for drugs
6 sold and reference standards.

7 Q Are those the standards in the USP
8 monographs?

9 A Yes.

10 Q You said that you've been involved
11 with the preparation and submission of ANDAs,
12 A-N-D-A-S; is that correct?

13 A Mm-hmm.

14 Q Yes?

15 A Yes.

16 Q Have you ever created a connection
17 with a ANDA risk assessment?

18 A Have I created a risk assessment
19 document?

20 Q Yes.

21 A We've done many risk assessments in
22 connection with and ANDA, in connection with NDA,
23 new drug application; we have developed a risk
24 assessment for any of our release testing. We do
25 this on routine basis.

1 Q In your experience do risk assessments
2 that are submitted in connection with an ANDA to the
3 FDA address the presence of impurities?

4 A Sometimes. Sometimes they do,
5 sometimes they don't. It really depends on how good
6 at CMC a person a company has and how good a chemist
7 they have and how they can -- if they, for example,
8 you have a drug that all of a sudden develops odor,
9 you know, sitting and it's causing odor or the drug
10 is changing, you've got to do risk assessment and
11 you need to submit it to the FDA.

12 And those risk assessments also, I would call
13 them a root cause analysis. They would need to go
14 to -- they could be very narrow. They could be very
15 extensive. It really depends on the company and it
16 depends on the team that's involved.

17 Q In your experience, does the drug
18 manufacturer identify the tests that the
19 manufacturer performed to evaluate risks associated
20 with the drug product at issue in the ANDA?

21 A Could you repeat your question? I
22 kind of lost my train of thought.

23 Q Sure. Does the drug manufacturer have
24 to identify in the risk assessment the specific
25 tests it performed in developing the assessment?

1 A Yeah. They should. They should. For
2 example, at any time you change the chemical
3 process, you change your synthetic route, any time
4 you change the cap of -- let's say you go from glass
5 to plastic, you need to do risk assessment; how is
6 that going to impact your drug.

7 You go from, you know, a prefilled syringe to
8 another prefilled syringe, you need to do risk
9 assessment. In this case, you know, we're getting
10 into the really nitty gritty of sort of liability
11 issues, Daniel but, you know, in this case they
12 should have -- they changed the chemical process.
13 They should have done what I call the structural sort
14 of drugs, they should look at the structural
15 concerned molecule and they should look at those
16 structural concerns and say what are the chances of
17 something going wrong with this and then do a proper
18 risk analysis and not just brush it under the table
19 or say this is just minor thing and go on with it.

20 You know, using, for example, John, sodium
21 nitrite, in the original process they didn't use
22 sodium nitrite, whereas in the, you know, in the
23 defendant's process almost invariably everybody used
24 sodium nitrite. Sodium nitrate is the same molecule
25 that you find in a lot of, you know -- it's a

1 nitrated food; you know. You get potential formation
2 of NDMA. That's where nitrosamine comes from, and
3 sodium nitrite are known to cause nitrosamine and
4 NDMA. So that's where the risk analysis went wrong.

5 MR. NIGH: I need to interject
6 something at this time. As you can see, there is a
7 seven page declaration. He has not gone into detail
8 in terms of his liability opinions and I would warn
9 counsel at this point if we are going into liability
10 opinions, we're not going to cover this ground
11 again. There's not going to be a second bite of the
12 apple at those topics.

13 MR. GISLESON: I am not going into
14 liability issues at all. I am specifically
15 addressing his point he's made a couple of times,
16 that in his view the defendants didn't do what they
17 should have done in connection with evaluating or
18 testing for NDMA and NDEA, and so I'm following up
19 on that.

20 MR. NIGH: Yeah. That's in large part
21 because of the questions that occurred earlier that
22 also touched upon liability. So to the extent we
23 are going to continue further and follow up on
24 liability, defense counsel could do so at their own
25 closing.

1 MR. TRISCHLER: And as you are aware,
2 the witness just went well beyond the scope of my
3 question to volunteer a bunch of information, which
4 is why I am also following up on it.

5 Q The bottom line, in your experience
6 the ability to instruct the manufacturer to perform
7 additional tests if the FDA believes the risk
8 assessment did not appropriately evaluate certain
9 risks; is that true?

10 MR. NIGH: Again, this is clearly
11 liability. The more you want to follow down that
12 tunnel, the more you are following up on liability
13 opinions. This is far outside the scope of his
14 declaration.

15 A Let's talk about NDMA levels, John.

16 MR. NIGH: Just because he voluntarily
17 gives information in response to one of your
18 questions that's also a liability question and
19 continue to go down that tunnel doesn't mean that
20 defense counsel is not opening the door to this
21 questioning, and they are not going to get a second
22 bite at the apple.

23 BY MR. GISLESON:

24 Q The FDA can direct additional tests if
25 it believes it appropriate when it evaluates a risk

1 assessment in an ANDA, correct?

2 MR. NIGH: Form objection.

3 A The FDA can ask for additional tests
4 if they determine it's necessary. By and large they
5 rely on the manufacturer's own risk assessment and
6 whether the manufacturer considers that a low risk,
7 medium risk, high risk.

8 So if the manufacturer says this is low risk
9 and CMC reviewer at the FDA reviews it and if they
10 also miss it, you know, so, John, it's really a
11 question of they miss it, these guys miss it, yeah,
12 but at the end of the day it's the manufacturer's
13 responsibility.

14 Q You testified that in your view, the
15 defendant's product shouldn't contain any NDMA or
16 NDEA. Are you aware that nitrosamines have been
17 found in cosmetics?

18 A Yes, I have been aware.

19 Q Are you aware that nitrosamines have
20 been found in tobacco and cigarette smoke?

21 A Yes.

22 Q Are you aware that nitrosamines have
23 been found in drinking water?

24 A Yes, I am aware of that.

25 Q Are you aware that people consume

1 processed foods that include nitrosamines?

2 A Yes, I am aware of that.

3 Q Including bacon, sausage and ham?

4 A Yes, I am aware.

5 Q Are you aware that beer can contain
6 nitrosamines?

7 A John, we have to qualify and put me on
8 record as saying the levels of nitrosamines are
9 extremely low in many of these instances. For
10 example, do you know this minimum level that's
11 acceptable to have nitrosamine in water?

12 Q It's a low level, but it exists,
13 correct?

14 A It's extremely low level. So
15 nitrosamine, every time you eat bacon, you may get a
16 little bit of nitrosamine. Your body has the
17 ability to detoxify so much. I don't want to get
18 outside of my area but, you know, low levels of
19 nitrosamine and high levels are different stories.

20 Q Those are the questions I have. Thank
21 you for your time.

22 A Thank you.

23 CROSS-EXAMINATION

24 BY MR. HARKINS:

25 Q Good evening, Dr. Najafi. Can you

1 hear me okay?

2 A Yes.

3 Q My name is Steven Harkins. I represent
4 the Teva defendants and I just have a few followup
5 questions for you here.

6 You mentioned a few guidances today both for
7 unidentified impurities and then for genotoxic
8 impurities. Do you recall that?

9 A Yes.

10 Q Are you aware of ICH, Q3A and Q3B?

11 A Yes, I am.

12 Q And those provides guidance on the
13 levels at which any impurity needs to be assessed to
14 the extent it's not in a drug substance, right?

15 A That's correct.

16 Q Are you comfortable with the term
17 qualification threshold?

18 A Yes.

19 Q And the qualification threshold in
20 ICH, Q3A and Q3B defines the level at which any
21 impurity; harmless, hazardous, needs to be assessed
22 and then analyzed, right?

23 A Mm-hmm.

24 Q And unknown impurities that don't meet
25 that threshold strictly under Q3A and Q3B don't get

1 assessed further --

2 MR. NIGH: Form objection.

3 Q -- is that correct?

4 A No, that's not correct. Again, it
5 goes back to -- I didn't catch. You're Steven.
6 Steven, it goes back to looking at the structure --
7 you know, the changes you're making; looking at the
8 structures that are involved in the chemistry, and
9 you need to anticipate these impurities.

10 If you are anticipating certain genotoxic
11 impurities, you need to test for it. It could be
12 extremely low levels that doesn't meet the ICH
13 guidelines you are referring to. That's where you
14 end up going to ICH M7. ICH M7 take effect here
15 where they talk about extremely low levels of
16 genotoxic compound. They talk about testing those
17 genotoxic compounds in aims test and various tests
18 and they set limits. And it also -- it's a matter of
19 how -- whether you have an episodic drug or a chronic
20 drug.

21 For example valsartan, my mom was taking
22 valsartan for ten years. Now she is taking, you
23 know, lisinopril for the last few years. So, you
24 know, it really depends. Once the drug becomes a
25 drug -- I call it life styling drug, then your

1 exposure time -- so you need to consider all of that.
2 And it goes back to the fact that you need to
3 anticipate this impurity and then look for them.
4 Otherwise, you know, you're chromatogram -- you have
5 this valsartan compound is like a huge peak and then
6 there are lots of little peaks and they don't test
7 for it because they are actually below the levels of
8 .1 percent, .2 percent. So they don't test for it
9 and it doesn't require it.

10 Q Doctor, I promise we will get to where
11 you want to go, but I was just asking specifically
12 under Q3A and Q3B, not subsequent guidelines which
13 we will address in just a minute. If the
14 qualification threshold for an unidentified impurity
15 is not met, then testing further on those unknown
16 impurities is not conducted pursuant to that
17 guideline; is that right?

18 MR. NIGH: Form objection.

19 A This is correct with the qualification
20 that I previously state. You need to anticipate
21 based on structures of concern and then test some of
22 those anticipated genotoxic compounds.

23 Q And you previously testified that the
24 levels for testing of genotoxic or potential
25 genotoxic impurities are far lower?

1 A Far lower, less than .1 part per
2 million, less than 0.1 parts per million, in the
3 case of nitrosamines, zero.

4 Q And that guidance is at least
5 generally laid out in ICH M7 which you laid out?

6 A ICH M7.

7 Q Roughly a thousand full difference
8 between the levels you might be looking at there?

9 A Yeah.

10 Q You also testified and you just
11 mentioned again there could be 100 little identified
12 impurities, 100 little unidentified peaks if you ran
13 it over, correct?

14 A Yes.

15 Q And even an HPLC test that you used
16 that showed those peaks, that would not be
17 identifying and quantifying each of those impurities
18 just by running a single test with a single set of
19 settings, right?

20 A You might see 100 little impurities.
21 Those are only UV ultraviolet active compounds. You
22 could also have another 100 that are not ultraviolet
23 active compounds. So now you see that's where, you
24 know, that's where people in need to anticipate
25 certain impurities.

1 Q And to actually assess or quantify any
2 of those, maybe, hundreds of tiny little peaks, you
3 would need specialized testing that was specifically
4 tuned to the impurity that you were looking at and
5 looking for?

6 A You need to have specialized
7 equipment. That's where we go to CGMP, current good
8 manufacturing practices, which really states that
9 don't use a typewriter to type your letter. Use a
10 computer to type your letter. You see, it's like
11 these manufacturers are still using typewriters in
12 the age of computer and word processor.

13 We have GCMS which is extremely easy to
14 operate, extremely simple and it comes with a library
15 of molecules stored in it, so all you have to do is
16 just point your cursor to certain impurity and it
17 tells you the molecular weight and it tells you
18 several possible compounds that might be.

19 Q And you would -- I'm sorry. Are you
20 finished?

21 A Yes.

22 Q So you would need a specialized test
23 to identify, for example here, the NDMA or NDEA
24 compound among all of those other little peaks you
25 might see?

1 A I wouldn't call it specialized
2 instrument. These are routine instruments that
3 almost every lab, every university, every company
4 has including, in fact I would hesitate to guess
5 that your clients -- you're representing Teva,
6 right?

7 Q I am.

8 A I know for a fact that Teva has
9 probably dozens and dozens of GCMS and LCMS at their
10 facility.

11 Q And simply running those tests over a
12 drug substance without having them specifically set
13 to the impurity that you are attempting to identify
14 would not allow you to identify and quantify that
15 impurity, correct?

16 A Repeat your question? I missed it.

17 Q Running an HPLC or any other test
18 method over an impurity without having that machine
19 specifically set to identify and quantify an
20 impurity that you are trying to identify like in DNA
21 or NDEA would not allow you to identify and quantify
22 that impurity is that correct?

23 A Running an HPLC would not help you
24 with those impurities that's correct.

25 Q And, for example, specialized test

1 methods like the ones you used in your work for
2 Valisure later were published eventually that
3 allowed those specific settings to be employed to
4 identify these impurities, correct?

5 MR. NIGH: Form objection.

6 A Steven, I would strike the word
7 specialized equipment, because to someone trained in
8 the art, specialized equipment means something that
9 only Lawrence Livermore laboratory has or some
10 cyclotron or something has. These are not
11 specialized equipment, but they need to be thinking
12 about and anticipating NDMA and NDEA and look at it,
13 that's all.

14 Q You're familiar with the testing
15 methods that were published by the FDA in connection
16 with nitrosamine recalls?

17 A Yes, I am.

18 Q Are you aware of those methods having
19 been published anywhere else before they were
20 published by the FDA in connection with the recalls
21 in 2018?

22 MR. NIGH: Form objection.

23 A I am not aware, but the methods -- you
24 know, don't need a method. You develop your
25 methods. There are hundreds of methods for testing

1 NDMA if you search the literature. There is a
2 method as early as 1970 for certain testing for
3 NDMA; very validated, very good method.

4 Q Doctor, imagine my question was
5 specifically with regard to methods for identifying
6 NDMA and NDEA which were published by the FDA in
7 2018 with respect to the nitrosamine issue. You're
8 familiar with those?

9 A Yes, I am.

10 Q And just to clarify, you're not aware
11 of those methods having been published anywhere
12 before that, are you?

13 MR. NIGH: Form objection.

14 A I am not aware of FDA publishing
15 method for NDMA. FDA doesn't publish methods to
16 test a lot of drugs. They get involved and, you
17 know, basically somebody when basically something
18 bad happens. A lot of methods that are developed,
19 are developed by industry such as companies like us.
20 We develop the method, we validate the method and
21 then we submit it as part of a CMC package for NDA
22 filing or ANDA filing to the FDA and those methods
23 go into the system.

24 FDA doesn't really get involved in developing
25 testing. And then ultimately USP gets ahold of those

1 methods and puts it into their, you know, monograph.

2 Q Doctor, you had never seen those
3 methods published anywhere else before 2018,
4 correct?

5 MR. NIGH: Form objection.

6 A I did not see FDA publishing those
7 methods. I am not aware. There might be -- there
8 might have been issued something before. I am not
9 aware, but there are other methods that you can go
10 to besides FDA for nitrosamine analysis.

11 Q Specifically those methods and I know
12 with respect to FDA you are not aware of anyone else
13 publishing those mods before 2018 are you?

14 A There are some methods outside of FDA.

15 Q Dr. Najafi, my question is specific to
16 those methods, just those methods for identified
17 NDMA and NDEA. You have not seen them anywhere else
18 FDA or otherwise before 2018, right?

19 MR. NIGH: Form objection.

20 A I answered the question already.

21 Q I believe you did, but can you please
22 just answer it for me so we have a clear record?
23 You hadn't seen those before 2018?

24 A I have not seen FDA publishing any
25 methods before prior to 2018, but I may have missed

1 it, but there are other methods on NDMA by other --
2 by admissions, by industry by other people and there
3 are multiple methods for NDEA analysis.

4 Q Dr. Najafi, I am not asking about
5 other methods. I am not asking about something that
6 you haven't seen. I am asking you, Dr. Ron Najafi,
7 had never seen any of those methods published
8 anywhere before 2018, correct?

9 MR. NIGH: Form objection.

10 A Steven, I think you're trying to get
11 your own, you know, question answered. You can go
12 ahead and answer it.

13 Q I am not trying to get -- you have
14 not, correct?

15 MR. NIGH: Form.

16 A What would you like to hear?

17 MR. NIGH: Form objection.

18 Q Whether you had seen those methods
19 published anywhere prior to 2018.

20 A I mentioned --

21 MR. NIGH: Form objection.

22 A -- I have not seen FDA publishing any
23 methods prior to 2018, but I may be wrong, you know.
24 It requires some diligence. There are many other
25 methods that have been published for NDMA analysis

1 by GCMS by other means that are in the literature.

2 Q Do you think you missed it or that you
3 are wrong?

4 A Next question, Steven.

5 MR. NIGH: Well, hold on. Let me do
6 the objection. I am going to say it's asked and
7 answered. I think we asked this question many times
8 and I will continue to warn that he doesn't have
9 anything in his declaration about testing methods
10 and this is really going down the liability path
11 even further.

12 I would just warn that to the extent
13 he discloses opinions that starts talking about
14 testing methods in the future, I think you all
15 covered this topic.

16 Q Dr. Najafi, there are other compounds
17 within the nitrosamine class, right?

18 A Yes.

19 Q And the nitrosamine class is just one
20 class of potential genotoxic compounds that are
21 addressed by GCMS and other guidelines, correct?

22 A Yes.

23 Q Do you know how many classes of
24 compounds or types of covered structure alerts there
25 are?

1 A There are at least five different
2 classes, four or five different classes of compounds
3 by FDA. It's mentioned in the ICH guidelines.

4 Q And there are other sources that
5 identify potential genotoxic compounds as well,
6 right?

7 A Yes.

8 Q And within each of those classes there
9 are numerous individual compounds, right?

10 A Correct.

11 Q It's not your testimony that a drug
12 manufacturer is required to perform testing for
13 every type of potential genotoxic compound on every
14 drug substance, is it?

15 MR. NIGH: Form objection. We're
16 getting way into the liability. At this point I am
17 going to instruct him not to answer, because I think
18 it goes far outside the scope of his opinion.

19 Q Dr. Najafi, is it your opinion that
20 the reason that these drugs are not equivalent to
21 the reference listed drug is because of the presence
22 of these impurities NDMA and NDEA?

23 A I believe the fact that they contain
24 these highly DNA active genotoxic impurities, it
25 makes the drug not equivalent and not the same and I

1 think it could have, you know, significant impact on
2 the drug's performance.

3 Q And correct me if I'm
4 misunderstanding, but I believe it's your testimony
5 that someone looking at the underlying route of
6 synthesis here should have identified the potential
7 for this specific compound and conducted testing for
8 it; is that right?

9 MR. NIGH: Objection. Scope.

10 Q I'm sorry. I didn't hear the answer.

11 THE WITNESS: Should I answer, Daniel?

12 MR. NIGH: Yeah, you can answer.

13 A Someone should have anticipated. Once
14 they changed the route of synthesis and given those
15 structural concern the molecules of structural
16 concern, they should have anticipated NDMA and they
17 didn't.

18 Also, Steven, I want to just to answer your
19 question on methods that are available, there is EPA
20 methods for NDMA testing that goes well before 2018,
21 well before. There are food testing, you know,
22 testing using NDMA for food and they are all using
23 GCMS.

24 Q I believe you testified actually that
25 someone skilled in the art of chemistry, I think

1 that was your phrase, it would have been obvious to
2 look for this, right?

3 A Right.

4 Q FDA had access to information on the
5 valsartan synthesis for all the API manufacturers
6 prior to 2018, correct?

7 A Yes, correct.

8 Q And just to confirm your testimony
9 that I believe you gave to Mr. Gisleson just a
10 moment ago, you're not aware of any statements from
11 the FDA prior to June 2018 to the manufacturers of
12 valsartan drug products that they should just test
13 their products for potential presence of
14 nitrosamines, are you?

15 A I am not aware of FDA stating that
16 they should be aware, but WHO has been on record for
17 stating to all manufacturers of drugs to watch for
18 NDMA. If you have compounds of structures of
19 interest such as sodium nitrite, they need to look
20 for NDMA and just because FDA reviewer missed it
21 doesn't mean the manufacturer should say okay, FDA
22 by and large relies on the manufacturer.

23 Q The FDA would have had the information
24 for the ZHP product, right?

25 A Yes.

1 Q They would have had the information
2 for the Mylan product?

3 MR. NIGH: Object to form. Outside
4 the scope.

5 Q I believe -- was that a "yes?"

6 A I assume.

7 Q Finally, I understand it's your
8 opinion that the level of NDMA or NDEA in the
9 product should be zero, right?

10 A That's correct.

11 Q And it's your opinion that any product
12 containing NDMA or NDEA at any level is not the
13 equivalent of RLD and, therefore, be misbranded,
14 adulterated and should be recalled?

15 MR. NIGH: Form objection. Outside
16 the scope.

17 A That is my position.

18 Q Do you recall being shown the Valisure
19 document which indicated that Novartis' valsartan
20 product contained NDMA earlier?

21 A Yes, I did see that.

22 Q Assuming that Valisure's data showing
23 levels of NDMA in Novartis' valsartan drug product
24 is correct, it's your opinion that that Novartis
25 drug product containing NDMA would be misbranded,

1 adulterated and should be recalled?

2 A Assuming that Valisure's testing is
3 correct, which I have no knowledge of whether that
4 testing was correct and I also do not have any
5 knowledge that Novartis is using their old synthesis
6 and they may be using a generic drug manufacturer to
7 make that drug product; assuming that data is
8 correct, it's my opinion that the drug -- that NDMA
9 should not be allowed to be sold; you know, the drug
10 should not be allowed to be sold with NDMA.

11 However, FDA has allowed this interim number, so it
12 hasn't been recalled.

13 Q But again -- and I understand your
14 qualification, assuming that to be correct and I'm
15 only asking it with regard to the products shown
16 there that did, according to that information
17 contain NDMA, it would be your opinion that that
18 product should be recalled as misbranded and
19 adulterated?

20 MR. NIGH: Objection. Outside the
21 scope of his opinion.

22 A So assuming that misbranded, that
23 definition is false and misleading statement, false
24 and misleading statement, right, that's the
25 definition of misbranded drug, and you have

1 carcinogenic impurities, then you have potentially
2 toxic compound that, you know, people don't know
3 about it and that is misleading to whoever is taking
4 the drug.

5 If I'm taking -- Steven, if I'm taking
6 valsartan and I'm assuming this has zero NDMA in it,
7 if I'm taking torovastatin, Lipitor, okay, I take it
8 every day for, you know, lowering basically
9 cholesterol and various things, I am assuming it's
10 free of any NDMA. It has zero NDMA.

11 Q And if that product, any product
12 contained any level of NDMA, it would be your
13 opinion that that product is misbranded, adulterated
14 and should be recalled? I am just trying to
15 understand.

16 A That is my position. That is what I
17 believe the product is not -- it's not being -- we
18 are misleading the public.

19 Q Thank you, Dr. Najafi. There is no
20 further questions from me.

21 THE VIDEOGRAPHER: Any other questions
22 from the room?

23 MR. TRISCHLER: Are there any other
24 questions on behalf of defense counsel?

25 MR. GISLESON: Not at this time.

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1 MR. NIGH: Okay. I would like to take
2 a break. I'd like to come back in 15 minutes.

3 THE VIDEOGRAPHER: The time is 4:16.
4 This ends Media Unit 5.

5 (A recess was taken.)

6 (After the recess the following
7 occurred:)

8 THE VIDEOGRAPHER: The time is now
9 4:56. This begins Media 6.

10 CROSS-EXAMINATION

11 BY MR. NIGH:

12 Q Doctor, I'd like to show you a
13 document from Canada and I will represent to you
14 that this was a document that was disclosed as part
15 of your materials considered and given to the
16 defense counsel as well. Now you weren't asked
17 about any of the health Canada testing by any of the
18 defendants, correct?

19 A That's correct.

20 Q I want to draw your attention to
21 page 9, if we can scroll down to page 9. Actually
22 let me go to the top first. Let me get to the top
23 here. Here you can see impurities found in certain
24 angiotensin two receptor blocker products also known
25 as sartans, correct?

1 A Correct.

2 Q And you could see at the top you can
3 see the Canada flag and it says government of
4 Canada; do you see that?

5 A Absolutely. Yes.

6 Q And you can also see the words "Health
7 Canada" there is as well. Do you see that?

8 A I see Health Canada, yes.

9 Q Okay. Let's go down to page 9.

10 THE VIDEOGRAPHER: Counsel, while
11 she's jumping to page 9, you didn't announce this is
12 going to be marked as an exhibit.

13 MR. NIGH: It will be marked as an
14 exhibit.

15 THE VIDEOGRAPHER: It will be the next
16 one in line.

17 MR. NIGH: I don't know what we are
18 on, but I don't think we are using anything that has
19 31, correct?

20 THE VIDEOGRAPHER: Yes. We have not
21 marked 31 yet.

22 MR. NIGH: So I'll start at 31. This
23 will be marked as Exhibit 31.

24 BY MR. NIGH:

25 Q And Doctor, do you see where it says

1 "Novartis Pharmaceuticals" and right next to it, it
2 shows the word Diovan?

3 A Yes, I do.

4 Q And do you see the ones above that
5 refer to valsartan -- Mylan valsartan, Mylan
6 valsartan. Do you see that?

7 A Yes, I do.

8 Q Now your understanding is that Diovan
9 is the name brand of valsartan, correct?

10 A Yes, that's correct.

11 MR. TRISCHLER: Dan, can I get a
12 standing objection to leading or are you going to do
13 it one time and just ask questions the way they are
14 supposed to be asked?

15 MR. NIGH: You know, if you want to
16 object to leading, you can. If you want to object
17 to form, you can.

18 MR. TRISCHLER: I guess I will.
19 Objection to form.

20 BY MR. NIGH:

21 Q So you see the name Diovan?

22 A Yes, I do.

23 Q Does that refer to name brand
24 valsartan?

25 A Yes, it does.

1 Q And does Mylan valsartan, does that
2 refer to generic?

3 MR. TRISCHLER: Objecting to the form
4 and foundation.

5 Q And Doctor, what is the name brand of
6 valsartan called?

7 A Diovan.

8 Q Okay, and next to that, let's scroll
9 back up to the top of this page. Do you see the
10 column that shows NDMA result and nanogram per
11 tablet and NDEA result and nanogram per tablet?

12 A Yes, I do.

13 Q Let's scroll down again to November
14 and if we can highlight where it shows not detected.

15 A Right.

16 Q Doctor, what does that refer to?

17 A That refers to no NDMA or NDEA was
18 detected for Diane.

19 Q So Health Canada detected no NDMA or
20 NDEA for their name brand Diovan?

21 A Yes, that's correct.

22 MR. NIGH: We can take this document
23 down. Let's pull up the valsartan petition that was
24 used earlier. I don't actually see an exhibit
25 number in my box.

1 MS. HILTON: That was the question I
2 have, if we actually gave this an exhibit number.

3 THE VIDEOGRAPHER: That was 28.

4 MR. TRISCHLER: I was going to say I
5 thought it was 28. Thank you.

6 BY MR. NIGH:

7 Q Doctor, my understanding is this
8 Valisure petition was marked 28. Do you recall
9 seeing this petition during your questions?

10 A Yes, I do.

11 Q Okay. Let's scroll down to page 9.
12 Now, Dr. Najafi, I believe earlier you said you
13 don't believe Emery Pharma was not disclosed, its
14 name was not disclosed as a part of this report.

15 A Yes.

16 Q What does that mean?

17 A That means that we were not involved
18 in testing any of these drugs that were listed on
19 this petition. Typically if we do get some of these
20 tested and corroborate data, you know, Valisure
21 would have listed us and cited us as being involved
22 in testing.

23 Q Okay. And here you can see valsartan
24 in Novartis and you can see there are a couple of
25 these show no NDMA detected, correct?

1 A That's correct.

2 Q Now, it doesn't say Diovan, correct?

3 A That's correct. There is no reference
4 to Diovan.

5 Q It says valsartan, correct?

6 A That's correct.

7 Q So do you know if this is Novartis
8 name brand medication or Novartis generic drug
9 medication?

10 A It could be name brand or generic,
11 Novartis generic. I have no idea.

12 Q Looking at this, you wouldn't be able
13 to tell us?

14 A No.

15 Q Okay. And also this petition doesn't
16 test for NDEA in any way in the Novartis pills,
17 correct?

18 A That's correct. It only tests for
19 NDMA and NDMS.

20 Q Doctor, let me ask you a couple
21 questions about chemical equivalents. A drug with
22 20,000 nanograms of NDMA would not be chemically
23 equivalent or the same as a drug with 14 nanograms
24 of NDMA, correct?

25 MR. TRISCHLER: Objection to job.

1 Q A drug with 10,000 nanograms of NDMA
2 would not be chemically equivalent as a drug with
3 14 nanograms of NDMA, correct?

4 MR. TRISCHLER: Object to form.

5 A No.

6 Q A drug with 96 nanograms or more of
7 NDMA would not be chemically equivalent as a drug
8 with 14 nanograms of NDMA, correct?

9 A That's correct.

10 MR. TRISCHLER: Objection to form.

11 Q All right. Let's take a look at the
12 next document. Now, Doctor, do you recall defense
13 counsel showing you some -- a document that included
14 a few pages of what's on the USP website?

15 A Yes, I do.

16 Q Now the USP website includes a lot
17 more information than what was given in that
18 document, correct?

19 A That's correct.

20 Q And you weren't shown this information
21 during defense counsel's questioning from the USP
22 website, correct?

23 A That's correct.

24 Q Now, this is the pathway here we can
25 see it's USP/our work/chemical medicines and the

1 title of this document is nitrosamine impurities,
2 correct?

3 A That's correct.

4 Q And we can stroll down to the bottom
5 of this page briefly and you can see the URL
6 address, correct?

7 A Yes. That's correct.

8 Q Let's go back up. Actually, I want to
9 direct your attention to this paragraph that says
10 companies are responsible for understanding their
11 manufacturing processes which includes identifying
12 and preventing the presence of unacceptable
13 impurities.

14 This involves developing new predictive
15 approaches along with using suitable methods to
16 detect and control these impurities as well as others
17 that may arise when making changes to manufacturing
18 processes. Did I read that information correctly?

19 A Yes, you have.

20 MR. TRISCHLER: Objection to form.

21 Q Now, Doctor, according to USP, who is
22 responsible for understanding their manufacturing
23 processes?

24 A Companies are responsible for
25 understanding their manufacturing processes, not USP

1 and not FDA.

2 Q And those companies, that would be
3 referring to companies that are manufacturing drugs,
4 correct?

5 A Companies who are manufacturing drugs,
6 in this instance the companies who are manufacturing
7 ARBs.

8 Q Dr. Najafi, according to USP do they
9 state that in order to detect unacceptable
10 impurities that manufacturers can rely simply on
11 outdated technologies and methods?

12 MR. TRISCHLER: Object to form.

13 A I think reading this, this is pretty
14 clear. You want to follow CGMP guideline and CGMP
15 specifically talks about updated equipment, you
16 know, the newest technology and in this instance
17 GCMS or LCMS are not new technologies and basically
18 just as it states, the method needs to be able to
19 detect and control impurities as well as others that
20 may arise when making changes to manufacturing
21 processes, making changes to manufacturing
22 processes. And the word "predictive" is the key
23 where they say the companies need to have a
24 predictive testify involved involving developing new
25 predict testify approach to identifying, you know,

1 impurities such as nitrosamines, the cohorts of
2 interest.

3 MR. NIGH: You can take this document
4 down.

5 Q Doctor, do you recall when plaintiff
6 Harkins was asking you questions about whether drugs
7 should be considered adulterated or misbranded?

8 A Yes, I do.

9 Q For the purposes of class
10 certification and the declaration that you have
11 offered, are you offering any opinions about whether
12 the defendants' valsartan containing drugs are
13 considered adulterated?

14 A I am not offering any opinion.

15 Q For the purposes of class
16 certification and the declaration that you offered,
17 are you offering any opinions about whether the
18 defendants' valsartan-containing drugs are
19 considered misbranded?

20 A No, I'm not offering any opinion.

21 Q Okay. I don't have any further
22 questions.

23 THE VIDEOGRAPHER: Counsel, just real
24 quick you didn't announce it, but the nitrosamine
25 impurities page we were just looking at, is that

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1 Exhibit 32?

2 MR. NIGH: Yes, Exhibit 32. Thank
3 you.

4 THE VIDEOGRAPHER: Excellent.

5 MR. TRISCHLER: Nothing from me, Dan,
6 subject to my prior reservations but I'm done.

7 MR. GISLESON: Nothing further from
8 Aurobindo.

9 MR HARKINS: Nothing from Teva.

10 MR. NIGH: Thank you, everybody.
11 Okay. Good night. Thank you.

12 THE VIDEOGRAPHER: The time is 5:08.
13 That concludes today's deposition.

14 (Deposition concluded 5:08 p.m.)
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C E R T I F I C A T E

I, MICHELLE L. DAWKINS, a Notary Public and Court Reporter of the State of New Jersey, do hereby certify that prior to commencement of the examination, RON NAJAFI was duly sworn remotely by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.



MICHELLE L. DAWKINS, CCR, RPR

CCR License No. 30XI00224400

RPR ID No. 805591

Notary Public of New Jersey

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1 DANIEL NIGH, ESQ.

2 dnigh@levinlaw.com

3 February 14, 2022

4 RE: In Re: Valsartan, Losartan, Et Al

5 2/3/2022, Ron Najafi, PhD (#5066624)

6 The above-referenced transcript is available for
7 review.

8 Within the applicable timeframe, the witness should
9 read the testimony to verify its accuracy. If there are
10 any changes, the witness should note those with the
11 reason, on the attached Errata Sheet.

12 The witness should sign the Acknowledgment of
13 Deponent and Errata and return to the deposing attorney.
14 Copies should be sent to all counsel, and to Veritext at
15 erratas-cs@veritext.com

16
17 Return completed errata within 30 days from
18 receipt of testimony.

19 If the witness fails to do so within the time
20 allotted, the transcript may be used as if signed.

21
22 Yours,

23 Veritext Legal Solutions
24
25

1 In Re: Valsartan, Losartan, Et Al

2 Ron Najafi, PhD (#5066624)

3 E R R A T A S H E E T

4 PAGE_____ LINE_____ CHANGE_____

5 _____

6 REASON_____

7 PAGE_____ LINE_____ CHANGE_____

8 _____

9 REASON_____

10 PAGE_____ LINE_____ CHANGE_____

11 _____

12 REASON_____

13 PAGE_____ LINE_____ CHANGE_____

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16 PAGE_____ LINE_____ CHANGE_____

17 _____

18 REASON_____

19 PAGE_____ LINE_____ CHANGE_____

20 _____

21 REASON_____

22 _____

23 _____

24 Ron Najafi, PhD

Date

25

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1 In Re: Valsartan, Losartan, Et Al

2 Ron Najafi, PhD (#5066624)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, Ron Najafi, PhD, do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10
11 _____
12 Ron Najafi, PhD

_____ Date

13 *If notary is required

14 SUBSCRIBED AND SWORN TO BEFORE ME THIS

15 _____ DAY OF _____, 20____.

16
17
18 _____
19 NOTARY PUBLIC
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25

[& - 2:48]

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[3 - accurate]

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[accurately - answer]

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[answer - aspects]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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